

PHARMACOTHERAPY

Comparative Study of Patients in Correct Usage of and Preference for the Swinghaler and Turbuhaler Multidose Inhalers

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Objective. Current dry powder inhalers (DPIs), introduced to overcome problems associated with pressurized metered dose inhalers (pMDIs), possess not only difficulties originating from their designs but also other barriers that prevent their correct usage. The authors of this study investigated the ease and correctness of use of Swinghaler, a new device in the form of multidose DPI, as well as the preference of the study participants for either a Swinghaler or a Turbuhaler. **Methods.** A total of 260 patients from Korea, China, Indonesia, the Philippines, Taiwan, and Thailand were prospectively recruited. Patients who had stable asthma, were more than 12 years old, had no experience with DPIs, and provided informed consents were included, whereas those with limited physical or intellectual ability and prior experience with any DPIs were excluded. **Results.** There were no group or time effects between the patients who were assigned to use a Swinghaler or a Turbuhaler first. Forty-one (16.1%) participants correctly performed the inhalation maneuver with a Swinghaler, whereas 28 (10.9%) did so with a Turbuhaler; the difference was not statistically significant. The overall assessment on the precise use of the devices indicated that there were no differences between Swinghaler and Turbuhaler usage. Comparing the preference scales between the two devices, the participants gave higher scores to the Swinghaler for all assessment items and were more satisfied with the Swinghaler compared with the Turbuhaler (78.5% vs. 55.0%, $p < .001$). **Conclusions.** The participants showed no difference in their ability to correctly use a Swinghaler when compared with a Turbuhaler and preferred the Swinghaler. These results suggest that the Swinghaler may be an effective and valuable tool for the management of airway diseases.

Keywords asthma, chronic obstructive pulmonary disease, dry powder inhaler, pressurized metered dose inhaler

INTRODUCTION

Asthma and chronic obstructive pulmonary disease (COPD) are common airflow-limiting diseases whose main therapeutic modality relies on inhalation devices. The advent of chlorofluorocarbon (CFC)-propelled pressurized metered dose inhalers (pMDIs) provided a considerable advance in the therapy of airflow-limiting diseases (1). However, widespread use of pMDIs has exposed several technical and practical problems (2). First, they require a high level of patient coordination (3), which led to the development of spacers and breath-actuated inhalers (4, 5). In addition, lung deposition with pMDIs that contain CFC or non-CFC propellants and surfactants is inversely

related to inspiratory flow. Thus, a higher inspiratory flow results in higher deposition in the oropharynx and, consequently, a lower level of lung deposition (6, 7). In addition to the problems mentioned above, many pMDIs that contain CFCs have atmospheric ozone-depleting effects (8). Thus, CFC propellants are currently being phased out and replaced with chlorine-free hydrofluoroalkanes (9).

Dry powder inhalers (DPIs) have been introduced to overcome the difficulties associated with pMDIs. Current commercially available DPIs are breath-actuated and therefore provide an inherent coordination between inhalation and drug delivery. In a comparison study between Turbuhalers and pMDIs, Welch et al. (10) reported that participants, despite that most of them have prior experience with pMDIs, require less time to master using Turbuhalers than pMDIs. In this report, the median time to device mastery was 3.67 min for Turbuhalers and 5.33 min for pMDIs, and participants rated that Turbuhalers were better than

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pMDIs on the Patient Device Experience Assessment ease of use and overall satisfaction with single-item scales and the four multi-item scales of pharyngeal symptoms, oral sensation, operational use, and inhaler attributes. The main disadvantage of DPIs is that they require a specific level of peak inspiratory flow (PIF) to ensure that a sufficient amount of drug to have a therapeutic effect is delivered to the lung. Specifically, effective delivery of the drug depends on the airflow through the inhalation device. Higher inspiratory flow through a DPI enhances drug delivery and provides better de-aggregation of the drug particles (11), thus resulting in improved lung deposition (12). However, this requirement may reduce lung deposition in children and in patients who have difficulties in generating sufficient inspiratory flow (13). Scintigraphic and pharmacokinetic deposition studies have shown that Turbuhalers deliver on average 20–30% of the metered dose to the lungs of adults (12). In addition to the difficulties originating from the design of DPIs, there are other barriers preventing their correct usage. For instance, among patients with no assistance other than the instructions included with the package insert, 6% of patients demonstrated the correct technique with Turbuhaler®, and after 3 days of use, 35% of patients were still unable to use it correctly (14). Therefore, improved devices with effective drug delivery need to be developed. The Swinghaler, a newly developed form of DPI, has drug reservoir in the center of the device with a specialized structure of the inhalation channel that reduces static electricity and drug aggregation during delivery (Figure 1).

The authors of this study recruited a total of 260 participants of various backgrounds from the Far East and South-East Asian countries and compared the correct use and preference of the participants between a Swinghaler, a new device in the form of multidose DPI, and a Turbuhaler. The authors investigated the participants' behavior and how to use the new device, Swinghaler, during an inhalation course and compared the result with that of one of the popular devices, Turbuhaler, to get informed of patient education and for development of new inhalation devices.

MATERIALS AND METHODS

Demographic Characteristics of the Study Participants

A total of 260 participants who were recently diagnosed with asthma were enrolled from six Asian countries between October 2006 and June 2007. This study was performed after acquiring the approval of each institutional board of review. The inclusion criteria were as follows: (1) subjects who were diagnosed with asthma, (2) subjects who were 12 years and older, (3) subjects who had no prior experience with either a Swinghaler or a Turbuhaler, and (4) subjects who provided written informed consent. The exclusion criteria were as follows: (1) subjects who were unable to understand and use the study devices because the participant declared that he/she was illiterate or had limited intellectual ability or obvious physical handicaps to perform inhalation process and (2) subjects having a family member who used either Swinghaler or Turbuhaler or in any other way being familiar with Swinghaler or Turbuhaler. Informed consent from minors defined by local legislations was obtained from their legal representatives.

Study Design

The study design and progress are illustrated in Figure 2. After an initial evaluation, participants of each country were randomly assigned to perform Swinghaler first and then Turbuhaler (Swinghaler First Group) or Turbuhaler first and then Swinghaler (Turbuhaler First Group) according to their assignment code with block randomization. The study used a crossover design and the investigators who evaluated inhalation process were concealed from the assignment of the study participants. The participants were asked to read the inset from each device and perform the inhalation maneuver in the standing position. During the process, the study coordinators guided the study procedure and provided instructions regarding the inhalation technique or answered questions concerning inhalation technique posed by the subjects. The inhalation process of the subjects was videotaped with their consent. After videotaping the inhalation procedure, the investigators asked the

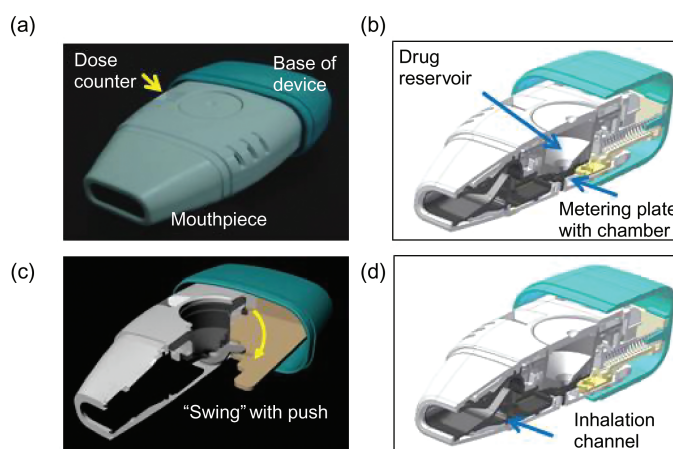


FIGURE 1.—The structure of a Swinghaler. (a) An outline of a Swinghaler. The Swinghaler is covered with a transparent protection cap. A dose counter is located on the side of the device. (b–d) A drug reservoir is located in the center of the device. The drug in powder form is placed on the metering plate within the metering chamber. The drug reservoir and the specialized structure of the inhalation channel reduce static electricity and drug aggregation during delivery.

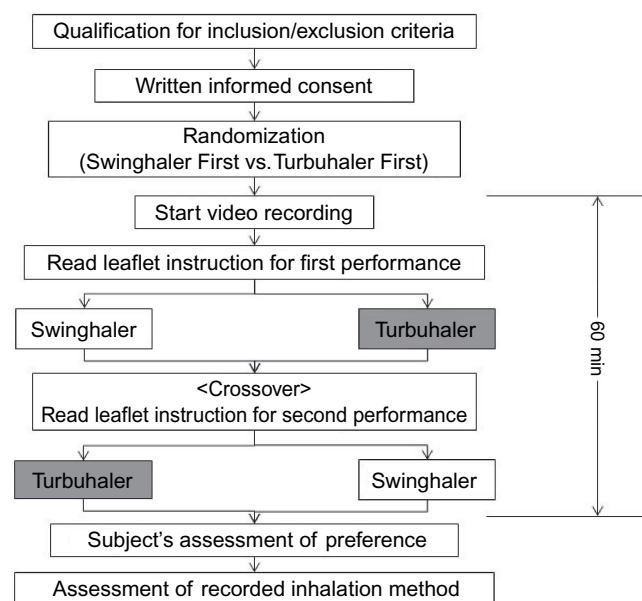


FIGURE 2.—A diagram of the study design. After the initial evaluation, participants who met the inclusion criteria and agreed to provide written informed consent were randomized and enrolled in the study process, which employed a crossover design. The study time, from reading the instruction leaflet to completing the inhalation maneuver, was limited to 60 min. At the end of the study, investigators asked each subject a series of questions regarding their perceived ease of use, correctness of use, and overall preference and recorded the subjects' responses.

subjects questions related to the ease and correctness of use and their preference regarding the two devices by using a questionnaire composed of the eight items listed in Table 4. Videotapes recording the inhalation process and case report forms were checked by local investigators and then sent to the principal investigator (Dr. Ahn) for scoring and further statistical analysis.

Investigated Items and Scoring Systems

Patient characteristics were analyzed on the basis of demographic data and medical history. The errors that frequently occurred when handling inhaler devices were reviewed (15, 16), and the parameters for inhaler-specific checklist were adapted from previous studies on inhalation devices (10, 17, 18). Eleven items were investigated during the use of Swinghaler (Supplementary Table 1 available online at <http://informahealthcare.com/doi/suppl/10.3109/02770903.2012.688910>) and 10 items were evaluated during the use of Turbuhaler (Supplementary Table 2). Among the 11 checklist items for Swinghaler and the 10 checklist items for Turbuhaler, a total of 9 parameters were compared between the two devices and were evaluated independently (Table 2). The parameters of “keeping the dose counter facing upwards” for the Swinghaler maneuver and “keeping the inhaler upright” for the Turbuhaler maneuver were compared with each other in terms of “proper positioning of the inhaler.” The parameters of “shaking the inhaler up and down 3 to 4 times” for the Swinghaler and “twisting the brown grip fully to the right as far as it will go” for the Turbuhaler were compared with each other in terms of “initiation of the devices.” The

parameters of “pushing the button of the inhaler toward the mouthpiece” of the Swinghaler and “twisting the brown grip back again fully to the left” for the Turbuhaler were compared with each other in terms of “triggering the devices.” The 10th item for the Swinghaler, “pushing the button one more time to make the inhaler return,” was not compared with any parameters for the Turbuhaler. Essential checklist items, which are critical for effective drug deposition in the lung, are selected for further analysis. Those during the use of the Swinghaler consist of six items: removing the cap from the inhaler, keeping the dose counter facing upwards, shaking the inhaler up and down 3 to 4 times, pushing the button of the inhaler toward the mouthpiece, inhaling fast and deeply, and pushing the button one more time to make the inhaler return. Those for the Turbuhaler consist of five items: removing the cap from the inhaler, keeping the inhaler upright, twisting the brown grip fully to the right as far as it will go, twisting the brown grip back again fully to the left, and inhaling fast and deeply (Supplementary Tables 1 and 2).

Analysis of the subjects' assessment was based on a 5-point scale (very dissatisfied, dissatisfied, neither dissatisfied nor satisfied, satisfied, and very satisfied) for both Swinghaler and Turbuhaler. After evaluating individual step of a participant's performance, the investigators assessed the participant's accomplishments as a whole with the 5-point scale (bad = 1, poor = 2, fair = 3, good = 4, and excellent = 5). When a participant received a score of 4 or greater for a given item, they were considered as having completed that item properly.

Statistical Analysis

A χ^2 -test was used for categorical data and a *t*-test or an analysis of variance (ANOVA) was used for analysis of continuous variables. Treatment effects, carryover effects, and period effects were tested with *t*-tests as appropriate for crossover studies. *P*-values less than .05 were considered statistically significant.

RESULTS

Demographic Characteristics and Medical History of the Participants

Demographic and clinical characteristics of the participants are summarized in Table 1. Among the 260 participants, 129 subjects (49.6%) were assigned to the Swinghaler First Group and the rest were assigned to the Turbuhaler First Group. Age distribution of each study group is described in Supplementary Table 3. There were no statistically significant differences in demographic characteristics of the participants in terms of nationality, gender, age, and educational background between the two groups. We also gathered the medical history of the participants that might influence the study results, such as duration of disease, duration of treatment, and period of experience with inhalation devices. There were no

TABLE 1.—Demographic characteristics and medical history of the participants.

	Swinghaler first group <i>n</i> (%)	Turbuhaler first group <i>n</i> (%)	<i>P</i> -value
Nationality			
Korean	29 (22.5)	30 (27.9)	1.000
Chinese	20 (15.5)	20 (15.3)	
Taiwanese	20 (15.5)	20 (15.3)	
Thailender	20 (15.5)	21 (16.0)	
Filipinos	20 (15.5)	20 (15.3)	
Indonesian	20 (15.5)	20 (15.3)	
Gender			
Male	62 (48.1)	63 (48.1)	.996
Female	67 (51.9)	68 (51.9)	
Age	Mean $\pm$ SD; (range) years	37.5 $\pm$ 17.31; 21–78	.680
Educational background			
Elementary school	9 (7.0)	8 (6.1)	.901
Junior high school	19 (14.7)	18 (13.7)	
High school	32 (24.8)	38 (29.1)	
Undergraduate degree	44 (34.1)	39 (29.8)	
Graduate school or higher	25 (19.4)	28 (21.4)	
Duration of disease	Mean $\pm$ SD; range (months)	120.5 $\pm$ 115.19; 0–624.0	.723
Duration of treatment		97.6 $\pm$ 108.70; 0–600.0	.976
Duration of inhalation device use		58.3 $\pm$ 79.22; 0–396.0	.234

TABLE 2.—Percentage of participants who correctly conducted checklist items.

	Swinghaler <i>n</i> (%) ^a	95% CI (Lower–upper)	Turbuhaler <i>n</i> (%) ^b	95% CI (Lower–upper)	<i>P</i> -value
Remove cap from inhaler	209 (82.0)	(77.24–89.68)	223 (86.8)	(82.63–90.91)	.134
Proper positioning of inhaler	135 (52.9)	(46.81–59.07)	188 (73.2)	(67.73–78.57)	<.001
Initiation of the devices	131 (51.4)	(45.24–57.51)	151 (58.8)	(52.74–64.77)	.093
Triggering of the devices	183 (71.8)	(66.24–77.29)	150 (58.4)	(52.34–64.39)	.002
Breath out and hold the breath	137 (53.7)	(47.61–59.85)	79 (30.7)	(25.10–36.38)	<.001
Place the mouthpiece between teeth and lips	222 (87.1)	(82.94–91.18)	222 (86.4)	(82.19–90.57)	.821
Inhale fast and deeply	166 (65.1)	(59.25–70.95)	155 (60.3)	(54.33–66.29)	.263
Exhale away from mouthpiece	152 (59.6)	(53.59–65.63)	149 (58.0)	(51.94–64.01)	.708
Close cap	252 (98.8)	(97.50–100.15)	244 (94.9)	(92.26–97.62)	.012

^aPercentage from a total 255 (missing = 5).^bPercentage from a total 257 (missing = 3).

statistically significant differences in clinical variables between the two groups (Table 1, Supplementary Tables 4–6).

Comparison of the Inhalation Technique between the Swinghaler and Turbuhaler

To investigate the handiness and appropriate use of the study inhalers by first-time users, we first compared individual items of each case report form with a χ^2 -test and then performed ANOVA with repeated measurement to identify device effect under the control of group and period effect in this crossover study. When the percentages of the participants who correctly conducted individual checklist items were compared, the participants were more likely to be accurate in “proper positioning of devices before use” when they used a Turbuhaler compared with a Swinghaler ($p < .001$, χ^2 -test). Conversely, the participants more precisely achieved the tasks of “triggering the device,” “breathing out and hold the breath,” and “closing the cap” when using the Swinghaler ($p = .002$, $p < .001$, and $p = .012$, respectively, χ^2 -test; Table 2).

Next, we compared the percentage of the subjects who performed the entire process correctly. Specifically, when a participant received a score ≥ 4 for each item of the inhalation process for a given device, the participant was considered as having conducted the entire process correctly. A total of 41 participants (16.1%) conducted all the checklist items correctly when one used a Swinghaler and 28 participants (10.9%) did with a Turbuhaler. Although more participants conducted all of the checklist items correctly with a Swinghaler than with a Turbuhaler, the difference was not statistically significant ($p = .086$, χ^2 -test; Table 3).

Additional analysis of three-factor ANOVA with repeated measurement in two factors was performed to distinguish the effect of group (Swinghaler First Group vs. Turbuhaler First Group) and period in crossover design. It revealed a difference caused by diversity of subjects ($p < .001$), but carryover effect was not statistically significant ($p = .170$). Analysis of period and device effect showed that both had statistically significant difference ($p = .019$ and $p = .001$, respectively; Supplementary

TABLE 3.—Percentage of subjects who conducted essential checklist items and all checklist items correctly.

		Correctly <i>n</i> (%)	95% CI (Lower–upper)	<i>P</i> -value
All checklist items	Swinghaler	41 (16.1 ^a)	(11.57–20.59)	.086
	Turbuhaler	28 (10.9 ^b)	(7.09–14.70)	
	Total	69 (13.5)	(10.52–16.43)	
Essential checklist items ^c	Swinghaler	64 (25.1 ^a)	(19.78–30.42)	.072
	Turbuhaler	83 (32.3 ^b)	(26.58–38.01)	
	Total	147 (28.7)	(24.79–32.63)	

^a Essential checklist items of each device are described in supplementary tables 1 and 2, respectively.

^b Percentage from a total 255 (missing = 5).

^c Percentage from a total 257 (missing = 3).

Table 7). When period effect was corrected, device effect was $68.1 \pm 0.95\%$ in the Swinghaler and $63.5 \pm 0.94\%$ in the Turbuhaler ($p < .001$; Supplementary Table 8).

Comparison of Essential Checklist Items

Among the items investigated, six items from the Swinghaler and five items from the Turbuhaler inhalation maneuver were selected as essential checklist items, which are critical for effective lung deposition of drug considering the specific design of each device. The percentage of the participants who conducted essential checklist items correctly was compared with the χ^2 -test, and then ANOVA with repeated measurement was performed to identify device, group, and period effect. When a score ≥ 4 for each checklist item was considered as correctly conducted by a subject, 64 subjects (25.1%) with the Swinghaler and 83 subjects (32.3%) with the Turbuhaler conducted all the essential checklist items correctly, although the difference was not statistically significant ($p = .072$, χ^2 -test; Table 3). With three-factor ANOVA with repeated measurement in the two-factor design to measure group, period, and device effect, there was a difference caused by diversity of subjects ($p < .001$), but period effect and device effect did not exist ($p = .053$ and $p = .0578$, respectively; Supplementary Tables 9 and 10).

Participants' Preference and Assessment of Devices

When the participants were asked regarding their subjective preference for each device by using a questionnaire composed of eight items listed in Table 4, the majority of the participants gave a higher score to the Swinghaler based on the inter-device preference scale comparison. Among the questionnaire items, “being able to see the number of doses remaining” received the highest score,

whereas “managing the hygiene of the devices” was only marginally preferred.

The participants' overall assessment on Swinghaler and Turbuhaler was analyzed using the 5-point scale (Table 5). There was statistically significant difference in the level of satisfaction between Swinghaler and Turbuhaler ($p < .001$, χ^2 -test). The percentage of the participants who gave score “neither dissatisfied nor satisfied” was significantly higher in the Turbuhaler use than in the Swinghaler use, whereas that of “very satisfied” was significantly higher in Swinghaler. The percentage of the participants who were either “satisfied” or “very satisfied” was significantly higher in Swinghaler, indicating that subject's satisfaction with the Swinghaler was much higher ($p < .001$, χ^2 -test).

Discussion

Airflow-limiting diseases such as asthma and COPD are common and have a major impact on the health of the population. The mainstay of treatment for these diseases is delivering medication at the site of the disease via inhalation. This process can be achieved by a number of different devices such as pMDIs, alternative pMDIs, DPIs, and nebulizers. Currently, DPIs including the Turbuhaler, Diskus, and Handihaler are the most commonly used devices for management of airway diseases (17, 19).

Although DPIs are considered easier to master and preferred over pMDIs, several studies reported that DPI devices can be difficult to use accurately (10, 20). For example, an assessment of the inhaler technique revealed that incorrect use of the DPIs is widespread, with up to 85% of patients using their inhaler ineffectively (21). Relentless development of inhalation devices has made products such as Diskus and Handihaler available (3). However, one report showed that inhaler-specific error rates are highest among

TABLE 4.—Subject preference between devices.

	Swinghaler <i>n</i> (% ^a)	95% CI (Lower–upper)	Turbuhaler <i>n</i> (% ^a)	95% CI (Lower–upper)	<i>P</i> -value
1 Understanding the instruction leaflet	113 (58.6)	(51.60–65.50)	80 (41.5)	(34.50–48.40)	.018
2 Using the inhaler in acute exacerbation	127 (61.7)	(55.01–68.29)	79 (38.4)	(31.71–44.99)	.001
3 Seeing the number of doses left	196 (87.1)	(82.73–91.49)	29 (12.9)	(8.51–17.27)	<.001
4 Managing the hygiene of the device	66 (60.0)	(50.84–69.16)	44 (40.0)	(30.84–49.16)	.036
5 Comfort carrying around	116 (72.1)	(65.12–78.98)	45 (28.0)	(21.02–34.88)	<.001
6 Device design	157 (75.1)	(69.25–80.98)	52 (24.9)	(19.02–30.74)	<.001
7 Overall ease of device use	126 (67.4)	(60.66–74.10)	61 (32.6)	(25.90–39.34)	<.001
8 Overall attractiveness	157 (80.1)	(74.51–85.69)	39 (19.9)	(14.31–25.49)	<.001

^a Percentages of patients who expressed a preference. When the study participant refused to answer to preference items or gave same preference, it was removed from analysis.

TABLE 5.—Subject's overall assessment.

	Swinghaler <i>n</i> (%)	95% CI (Lower–upper)	Turbuhaler <i>n</i> (%)	95% CI (Lower–upper)	<i>P</i> -value
Very dissatisfied	9 (3.5)	(1.24–5.68)	7 (2.7)	(0.72–4.66)	
Dissatisfied	11 (4.2)	(1.78–6.68)	27 (10.4)	(6.68–14.09)	
Neither dissatisfied nor satisfied	36 (13.9)	(9.65–18.04)	83 (31.9)	(26.3–37.59)	
Satisfied	111 (42.7)	(36.68–48.70)	112 (43.1)	(37.06–49.10)	
Very satisfied	93 (35.8)	(29.94–41.60)	31 (11.9)	(7.98–15.86)	
Total	260		260		<.001

Handihaler users (53.1%) followed by Turbuhaler (34.9%) and Diskus users (26.7%) (15).

Another DPI, Swinghaler, was designed for effective drug delivery and to overcome the error-prone process that frequently troubled users during the inhalation maneuver with the current DPIs. To initiate this device, patients push the base of the device which subsequently swings the device open (Figure 1a and c). The portion that covers the drug reservoir and the metering chamber with a metering plate employs a specialized material, poticon, and is designed specifically to reduce static electricity. Poticon is a composite plastic material made of TISOMO (titanium acid potassium fiber shown with $K_2O \cdot nTiO_2P$) and is named after Potassium Titanate Compound. The inhalation channel was also designed to reduce static electricity and prevent aggregation of drug particles within the channel. However, these attempts for effective drug delivery have not been validated yet and require additional studies.

The dose counter and the structure of mouthpiece were redesigned for easy and convenient use of the device. Easy use, especially during an acute attack, and the presence of a dose counter are regarded as important features of ideal inhalers. The location and readability of dose counter resulted in the participants giving a higher score in the preference survey (Table 4), but this did not help the participants pose a proper positioning of the device. However, this design of dose counter appears to be helpful for “triggering the device.” Proper positioning of the mouthpiece between the teeth and lips is one of the important steps for current DPIs (Table 2). A previous study showed that the error rate with inhalers increases with age and with severity of the airway obstruction (15). In this study, we did observe increased error rate in the investigated items with age (Supplementary Table 11). When a linear regression model was applied, the percentage of correct use of Swinghaler was higher in younger age groups, but this percentage decreased more steeply than that of Turbuhaler with the increase of age, reaching no difference in the age group more than 60 years (data not shown). A few age groups in this study such as age groups 12–19, 20–29, and 50–59 years used Swinghaler more correctly than Turbuhaler. Notably, there was no difference in the percentage of correct use of both devices in the age group 30–39 and 40–49 years. Because the participants who were having a family member who used either the Swinghaler or Turbuhaler or in any other way being familiar with Swinghaler or Turbuhaler were not enrolled in this study, we excluded the possibility of experience

from daily social activities in these age groups. However, we could not figure out the reason for variations in the percentage of correct use among age groups from additional analysis.

In this study, we compared the correctness of use of and the participants' preference for the Swinghaler, a new form of DPI, with those of the Turbuhaler. For evaluation of correctness of use, we compared items of each study device in several aspects such as comparison of individual item, sum of study items, sum of essential checklist items, ANOVA with repeated measurement, and investigator's overall assessment. We were not able to conclude that one device was superior over the other in terms of correctness of use.

In conclusion, the participants showed no difference in their ability to use the two devices with respect to the checklist items. There was no statistically significant difference between the subjects who conducted all checklist items correctly with the Swinghaler and those with the Turbuhaler. Participants' subjective preference and satisfaction with the Swinghaler was significantly higher, indicating that Swinghaler may be an effective alternative tool for the management of airway disease.

CONCLUSIONS AND KEY FINDINGS

The authors compared the correct use and preference between Swinghaler, a new device in the form of multidose DPI, and Turbuhaler. There were no differences in the correctness of inhalation maneuver between the two devices and the study participants preferred Swinghaler, suggesting that Swinghaler is an alternative tool for management of airway diseases.

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DECLARATION OF INTEREST

None of the authors has a conflict of interest to declare in relation to this work.

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