Observational Study

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Improved inhaler handling after repeated inhalation guidance for elderly patients with bronchial asthma and chronic obstructive pulmonary disease

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Abstract

Accurate evaluation of inhaler handling is essential for improved treatment of bronchial asthma (BA) and chronic obstructive pulmonary disease (COPD). Many studies have described the correlation between age, inhalation guidance, and procedure improvement. Elderly patients should receive proper inhalation guidance. This was a retrospective open cohort study conducted at a single hospital with outpatient open pharmacies that provided inhalation guidance to patients of BA and COPD. A total of 525 cases were included in the study. The median age was 71 years with no significant difference between genders (males: 71 ± 16.0 years; females: 72 ± 16.1 years; $P = .24$). There were 226 males (43.0%) and 299 females (57.0%; $P = .03$). BA was significantly more prevalent than COPD ($P < .001$). There was no significant difference in dry powder inhaler (DPI) and pressurized metered-dose inhaler (pMDI) visits in those <60 years of age ($P = .23$). pMDI was used significantly more often than DPI in those aged 60 to 90 years of age ($P < .001$). In both <70 and >70 years of age, the most common error with DPI use was improper inhalation speed, which reduced (improved) at the third visit. Gargling errors were most common with DPI use at the second visit and with pMDI at the first visit in both age groups, which subsequently reduced rapidly. Continuous repeated guidance steadily and significantly decreased errors with all devices ($P < .001$ for DPI, pMDI, and soft mist inhaler). Elderly cases (>70 years of age) should undergo continuous repeated guidance to reduce inhalation errors like inhalation speed and gargling errors.

Abbreviations: ACO = asthma–COPD overlap, BA = bronchial asthma, COPD = chronic obstructive pulmonary disease, DPI = dry powder inhaler, pMDI = pressurized metered-dose inhaler, SMI = soft mist inhaler.

Keywords: bronchial asthma, COPD, elderly, inhalation guidance, inhaler, inhaler errors, pharmacist

1. Introduction

The dry powder inhaler (DPI), pressurized metered-dose inhaler (pMDI), and soft mist inhaler (SMI) are the main players in treating outpatient bronchial asthma (BA) and chronic obstructive pulmonary disease (COPD).[1–3] Elderly COPD cases have increased in Japan.[4] Poor inhalation leads to a negative prognostic impact,[5] whereas correct inhalation of the prescribed medications is associated with improved health status and lung function.[6,7] However, pharmacological adherence to inhalers is poorer than that to oral medicines due to their handling difficulty.[8]

There are various device types and inhalation procedures, and different inhalers are frequently prescribed based on the disease status, leading to new inhalation errors.[9–11] Inhalation guidance is required for proper use, but doctors are unable to spend enough time evaluating inhalation errors during the limited outpatient clinic time in Japan. Some regional core hospitals provide effective treatment by collaborating with out-of-hospital pharmacies.[12] Pharmacists uniquely demonstrate better clinical outcomes in patients with BA since they have clinical expertise in educating cases.[13] Out-of-hospital pharmacies have been continuously addressing the disease condition by evaluating patients' inhalation procedures and sending reports to the regional core hospital.[14]

Previous inhaler studies have reported various risk factors for inhaler handling errors. Web-based inhalation guidance and nurse consultations have been reported.[15,16] Device types and case profiles are critical,[17,18] and poor socioeconomic status and a low education level are other risk factors.[19] Various reasons have been reported due to different case population characteristics, study settings, and diseases.[20] Reports on inhalation guidance in elderly cases are especially limited.[21]

We studied face-to-face guidance for elderly patients at a single hospital to easily evaluate guidance quality. This study aimed to examine whether continuous inhalation guidance provided by an out-of-hospital pharmacy could improve the inhalation procedure, even in elderly patients.[22]

The author has no funding and conflicts of interest to disclose.

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request for privacy.

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2. Methods

We performed a retrospective open cohort study at a single hospital with outpatient open pharmacies. Patients of BA, COPD, and asthma–COPD overlap (ACO) who visited any of these outpatient open pharmacies for inhalers received inhalation guidance. The inhalation procedure was evaluated using guidance sheet questionnaires that had priorly been discussed with the pharmacists.[23,24] We decided to use 70 years as the cutoff age to determine inhalation understanding.[25]

The translated (from Japanese) parameters of the guidance sheet included the following:

- Identification number
- Name
- Date of birth
- Guidance date
- Number of guidance visits
- Disease (BA, COPD, ACO)
- Inhaler (product name)
- Inhaler type (DPI, pMDI, SMI)
- Recognition of dosage (good, poor)
- Recognition of continuous treatment need (good, poor)
- Drug set (good, poor)
- Exhalation before inhalation (good, poor)
- Proper inhalation speed (good, poor)
- Breath hold for 2 seconds after inhalation (good, poor)
- Gargling after inhalation (good, poor)

Guidance was provided through multiple outpatient open pharmacies. At each visit, the patient received practical guidance from the pharmacists. The same guidance procedure and assessment methods were performed at each visit. The pharmacists evaluated each procedure as either good or poor. To confirm whether the pharmacist's guidance was appropriate and to minimize evaluator bias by each pharmacist, all pharmacists in charge of the pharmacist's inhalation guidance method were confirmed in advance by a pharmaceutical manufacturer.[26] Pharmacists were randomly chosen when each patient visited. Guidance was provided in a separate private space by verbal, practical, and face-to-face instruction with specific inhaler training kits and guidance sheets. Recognition of dosage was considered good if the patient understood how many times and when the inhaler should be used. Recognition of continuous treatment need was considered good if the patient understood the importance of continuous treatment. The drug set was considered good if the patient could individually and correctly prepare the inhaler (in front of the pharmacist) before inhalation (i.e., pharmacists confirmed that the DPI, pMDI, and SMI drug set procedures were correct). Exhalation before inhalation was considered good if the patient exhaled completely before inhalation. The inhalation speed of DPI was checked using a training kit. pMDI and SMI require slow inhalation. Breath hold was considered good if the patient could hold their breath for 2 s after inhalation. Gargling after inhalation was considered good if the case understood the need for gargling after each inhalation, which was asked by the pharmacist. The anonymized guidance sheets were returned to our hospital for retrospective analysis.

At first use of the inhaler, patients provided consent and started receiving guidance. They also received guidance every 1 to 3 months or at the time of changing the device. The exclusion criteria were as follows: patients who started inhalers without guidance before providing consent, those who could not inhale on their own, those who refused to participate in the study, those who did not send back guidance sheets, and those <20 years of age.

The guidance number began from the first guidance (after consent) and was counted at each visit during the study period. Therefore, even if the same person received guidance multiple times, it was included in the total number of visits. Patients that used >2 devices, such as DPI plus pMDI, were counted separately. D'Agostino's K-square test was used to check for normality of distribution.

The study period was from January 1, 2020, to December 31, 2021. R version 3.5.3 (The R Project, Vienna, Austria) was used for the statistical analysis. A 2-tailed Mann–Whitney *U* test was used to compare the 2 unpaired groups (errors and case age), and the χ^2 test was used to compare differences in expected frequency (gender and age groups). The Kruskal–Wallis test was used to compare >3 groups (devices and visit times). The significance criterion was set at $P < .05$ (Tukey–Kramer test). This study was approved by the Ethical Committee of the Kurihara Central Hospital (approved number is 2-14). Because the study period was limited, we evaluated all the included cases to enhance the calculation power.

3. Results

The characteristics of the 525 cases enrolled during the study period are shown in Table 1. The number of females was significantly higher than that of males ($P = .03$). The mean age was 71 years, with no significant difference between males (median, 71 years; interquartile range [IQR], 63–79 years) and females (median, 72 years; IQR, 64–81 years; $P = .24$). BA was significantly more prevalent than COPD (297 cases vs 159 cases; $P < .001$). ACO was excluded from the evaluation to avoid double counts (i.e., because ACO contains both BA and COPD).[27]

Figure 1 shows the prevalence of cases by disease and age. BA cases were significantly more prevalent than COPD cases in all age groups except in those ≥90 years of age. This tendency was obvious in those <70 years of age. In all age groups, the difference was significant (BA vs COPD, BA vs ACO, $P < .001$).

The devices used in each group are shown in Figure 2. There was no significant difference in DPI and pMDI use in those ≤59 years of age. There was no pMDI spacer device user among all patients. pMDI was used significantly more often than DPI in those aged 60 to 90 years of age ($P < .001$) The ≥90 years group was too small to evaluate, and SMI was also excluded from the analysis because of its limited use among the cases.

The total number of handling errors with DPI, pMDI, and SMI are shown in Figure 3. DPI errors were dominant in those <59 years of age, whereas among those ≥60 years of age, pMDI errors increased to as many as DPI errors ($P = .57$). Compared to the device used in Figure 2, among those ≥60 years of age, the DPI error rate might have been higher than that for pMDI.

Figure 4 describes the types of handling errors reported in those under and over 70 years of age. Elderly cases tended to have more errors than younger cases.[17] In both age groups, the most common error with DPI use was improper inhalation speed, which reduced (improved) at the third visit. This indicates that proper inhalation speed should be evaluated even in those <70 years of age. Gargling errors were most common with

Table 1

Characteristics of the cases enrolled during the study period.

		n (%) or mean ± SD	*P*
Gender	Total	525 (100)	.03
	Male	226 (43.0)	
	Female	299 (57.0)	
Age	Total (yr)	71 ± 16.0	.24
	Male (yr)	71 ± 13.7	
	Female (yr)	72 ± 16.1	
Disease	BA	297 (56.6)	>.001
	COPD	159 (30.3)	
	ACO	69 (13.1)	

Data are expressed as the mean ± standard error or as the number (%).
ACO = asthma–COPD, BA = bronchial asthma, COPD = chronic obstructive pulmonary disease.

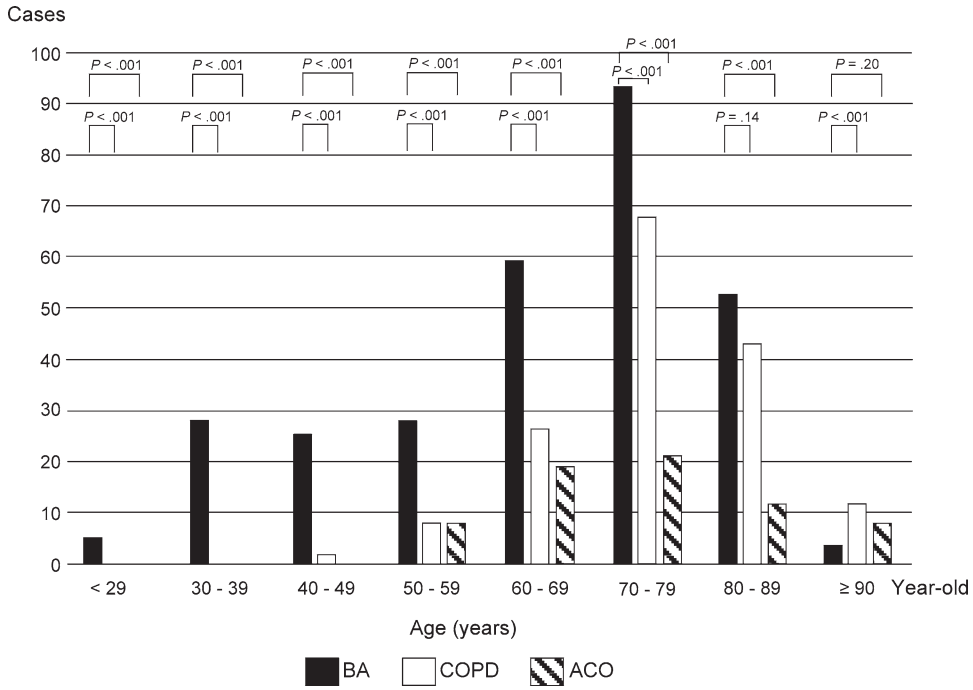

Figure 1. Prevalence of cases by disease and age. ACO = asthma–COPD overlap, BA = bronchial asthma, COPD = chronic obstructive pulmonary disease.

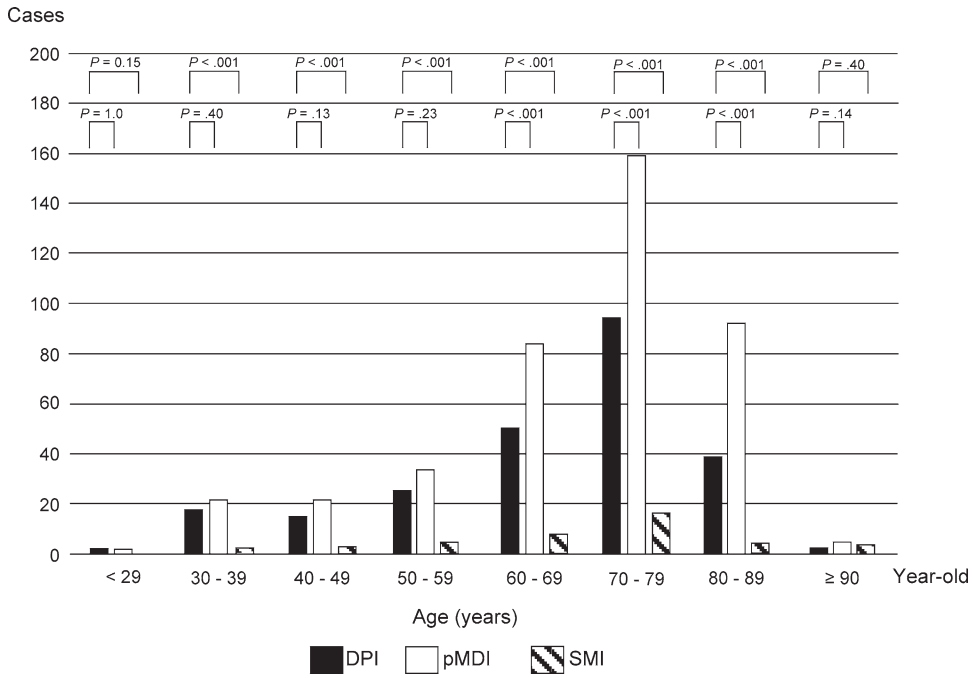

Figure 2. Devices used by each age group. DPI = dry powder inhaler, pMDI = pressurized metered-dose inhaler, SMI = soft mist inhaler.

DPI use at the second visit and with pMDI at the first visit in both age groups, which subsequently reduced rapidly.

Figure 5 shows the number of guidance visits and observed handling errors. DPI errors were the highest in the second guidance visit, and pMDI errors were highest at the first guidance visit. A significant difference was only identified during the second and third visits ($P < .001$). A decreased number of errors was associated with continuous repeated guidance, and >3 guidance visits were found to be effective for optimal inhaler use. However, ≥7 guidance visits increased the number of handling errors.

Figure 6 shows the number of handling errors with repeated guidance visits in those <70 and >70 years of age. Logistic regression analysis was not performed to focus on continuous repeated guidance. DPI, pMDI, and SMI errors varied significantly with the number of guidance visits and age. SMI showed the highest error of 7 at the first visit in those >70 years of age. Although the first and second visits showed a high number of errors in elderly cases, continuous repeated guidance steadily and significantly decreased errors with all devices ($P < .001$ for DPI, pMDI, and SMI).

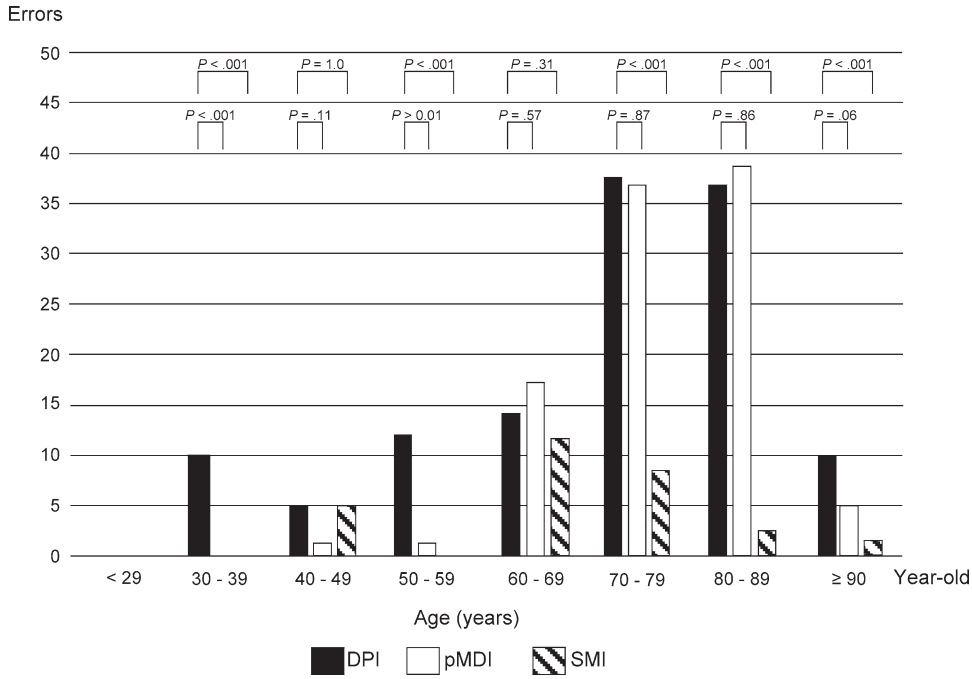

Figure 3. Total inhaler handling errors during the study period. DPI = dry powder inhaler, pMDI = pressurized metered-dose inhaler, SMI = soft mist inhaler.

Visit	DPI 1st	DPI 2nd	DPI 3rd	pMDI 1st	pMDI 2nd	pMDI 3rd
Under 70 years of age						
Dosage	0	0	2	0	0	0
Continuity	0	1	1	2	1	0
Drug set	0	1	0	0	1	0
Exhalation	0	1	2	2	1	0
Inhalation speed	3	5	1	2	1	0
Breath hold	0	1	1	2	0	0
Gargling	1	3	0	7	0	0
Under 70 years of age						
Dosage	2	1	0	1	0	0
Continuity	4	1	1	2	0	0
Drug set	2	2	1	2	2	1
Exhalation	0	2	0	2	0	0
Inhalation speed	7	6	1	2	0	0
Breath hold	1	0	0	2	1	3
Gargling	0	6	2	5	0	0

Case Number: 0 1 2 3 4 5 6 7

Figure 4. Inhaler handling errors with DPI and pMDI stratified by age. DPI = dry powder inhaler, pMDI = pressurized metered-dose inhaler.

4. Discussion

Continuous repeated guidance for elderly patients steadily decreased inhaler errors with both DPI and pMDI, despite elderly patients having been reported to have high handling errors with these devices.[28,29] In our study, the inhalation speed of DPI and gargling after DPI and pMDI were the most commonly reported errors in elderly patients. Elderly patients >70 years of age showed improved inhalation speed and gargling errors for DPI at the third visit. For pMDI, gargling was the most commonly observed error in the first visit in those under and over 70 years of age. We hypothesized that younger patients may also be confused at the first visit because pMDI requires multiple rounds of gargling daily. As expected, the second visit showed a reduced gargling error with pMDI. Patients using DPI learned gargling for the first time with a few errors. The second visit evaluation revealed poor gargling in cases with a sore

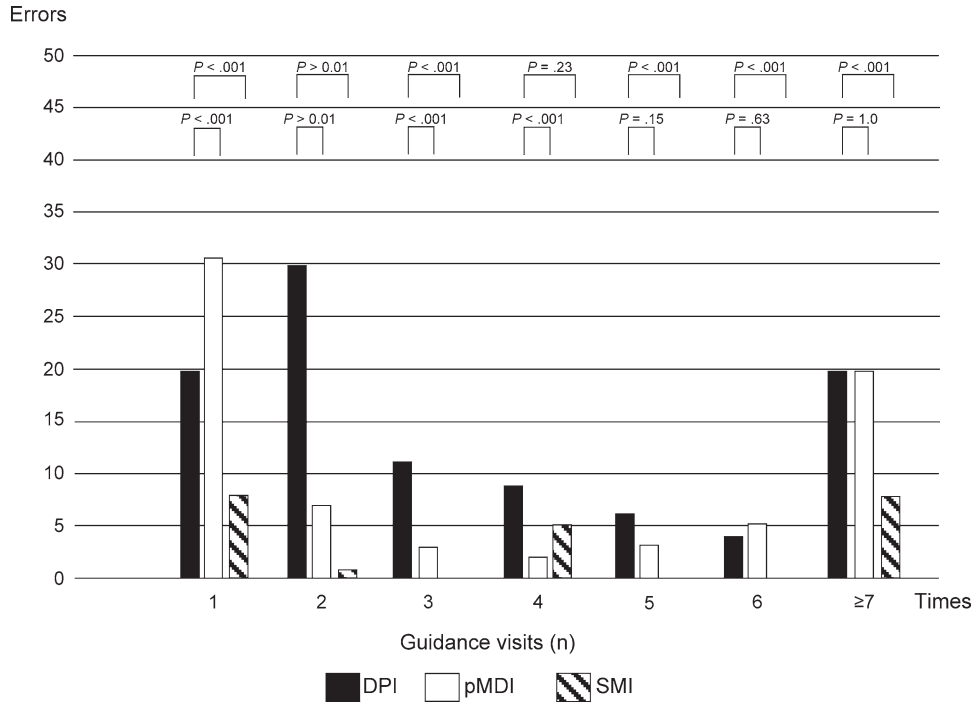

Figure 5. Inhaler handling errors stratified by device and number of guidance visits. DPI = dry powder inhaler, pMDI = pressurized metered-dose inhaler, SMI = soft mist inhaler.

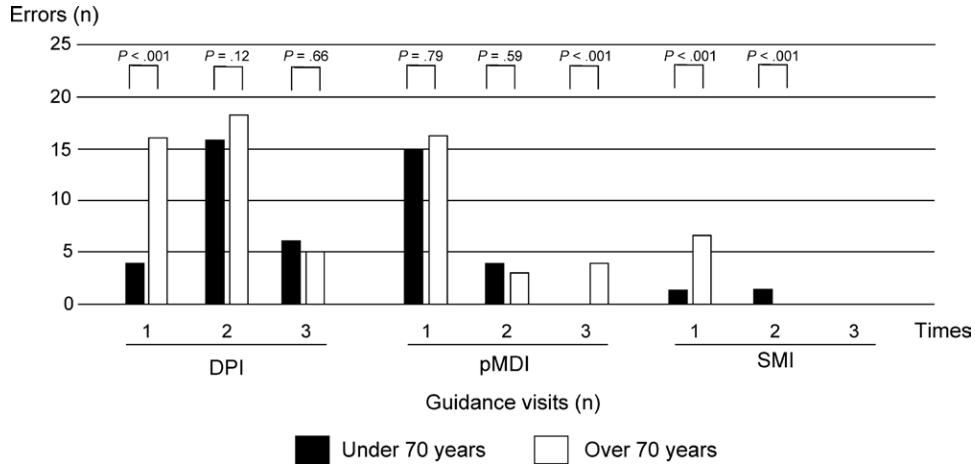

Figure 6. Inhaler handling errors stratified by device, number of guidance visits, and age. DPI = dry powder inhaler, pMDI = pressurized metered-dose inhaler, SMI = soft mist inhaler.

throat. One patient inhaled pMDI before breakfast, resulting in skipping gargling in the morning because the case considered taking breakfast could replace gargling to wash the oral cavity. pMDI gargling guidance was first provided as a series of procedures. pMDI requires gargling after every inhalation. The pharmacist insisted on the importance of gargling for pMDI, leading to a decrease in errors by the second visit. Repeated training was more effective than a single intensive inhaler training.[30]

Our results revealed much fewer errors than those reported previously.[31] The precise investigation of inhaler handling mean errors was 20.0% in all visits. In many reports, handling errors were only evaluated at the first visit, whereas we observed for improvement over 2 years with multiple guidance visits. One report concluded that inhalation speed and exhalation before inhalation errors were common and that most were restitutive.[32] Although their first errors differ from ours, their final opinion that continuous guidance may lead to proper treatment is similar to ours. At least 3 guidance visits are required for improving the inhalation procedure,[33] as higher education leads to better results.[34] More long-term observation may enhance this conclusion. Another report showed similar risk factors at the first visit but did not discuss the importance of continuous repeated guidance.[34]

A discrepancy between self-evaluation for the current procedure and self-evaluation with the current device is commonly observed.[35] This treatment gap occurs when clinical features require step-up treatment or do not match between symptoms reported by the patients and signs observed by doctors. Doctors consider sputum and fatigue as negative signs of BA and COPD, while patients do not complain of these symptoms because they do not seriously affect their daily lives. Doctors need to use objective biomarkers to better evaluate patients. This discrepancy might have disoriented the quality of our study. The treatment gap with a long inhalation history, as in > 7 of our

cases, might have been due to worse symptoms[36] without self-notification, Self-perceived barriers to BA further complicate this problem.[37] Moreover, most Japanese COPD cases are overlooked.[38] COPD patients in Japan have worse adherence barriers than BA patients.[39] However, device-satisfied cases show better outcomes.[40] Many patients need to use inhalers with fewer errors. Novel drug delivery systems may improve inhalation errors.[41] Our study did not include self-evaluation and objective biomarkers.

The limitations of this study include the following: ambiguities regarding why the errors increased (>7 times) and why pharmacists considered all cases not suitable for pMDI spacer devices; analyzing both ellipta and turbuhaler as DPI together;[42,43] poor evaluation of cases using multiple devices;[44] one report evaluating each device;[36] no consideration for whether the errors were device-independent error or device-dependent;[45] no use of objective parameters such as ACT/CAT or lung function test;[46,47] inherent bias due to the retrospective design of the study; and the inability to generalize the results to different populations (only conducted on Japanese patients). Face-to-face guidance takes time and surveys only a limited area.

We demonstrated that elderly patients >70 years of age are eligible for continuous repeated guidance to reduce inhalation errors like inhalation speed and gargling errors. Because the inability of BA patients to correctly use inhalers correlates with poor asthma control,[8] hospital and out-of-hospital pharmacy collaborations may improve the inhalation procedure even in the elderly.[48]

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Author contributions

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