

ORIGINAL RESEARCH

# Preference for Easyhaler® Over Previous Dry Powder Inhalers in Asthma Patients: Results of the DPI PREFER Observational Study

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<sup>1</sup>Unidad de Asma, Hospital Universitario Virgen del Rocio, Sevilla, Spain; <sup>2</sup>Unidad de Asma, Hospital Universitario Virgen Macarena, Sevilla, Spain; <sup>3</sup>Orion Pharma Iberia, Madrid, Spain; <sup>4</sup>Orion Pharma Corporate, Espoo, Finlandia; <sup>5</sup>Unidad de Gestión Clinica Alergología, Hospital Virgen Macarena, Sevilla, Spain **Objective:** To study patient preference for and satisfaction with the Easyhaler<sup>®</sup> device and to assess ease of training and use of the inhaler in patients previously treated with a variety of dry powder inhalers (DPIs).

**Methods:** We designed a non-interventional, cross-sectional, single-visit observational study of adult patients with persistent asthma referred to specialized care who had previously been treated with DPI inhalers for at least 3 months. Once clinical baseline data had been checked, patients filled in questionnaires on asthma control (GINA 2019), Feeling of Satisfaction with the Inhaler (FSI-10), and adherence (TAI and Morisky-Green questionnaires). Thereafter, all patients were trained in the use of Easyhaler. We assessed ease of use and satisfaction (FSI-10) with Easyhaler, as well as inhaler device preferences.

**Results:** We recruited 502 patients (mean age,  $50.2 \pm 16.2$  y; 63.1% female), of whom 485 were evaluable. In response to the main objective of the study, we compared the values of the self-completed adapted FSI-10, to measure satisfaction with the inhaler. A significantly higher score in each item of the questionnaire was recorded for Easyhaler. Overall, 38% of patients showed exclusive preference for Easyhaler (compared with 15% for the previous device) or were evenly matched in 46% of cases.

**Conclusion:** In the present study, Easyhaler achieved better patient ratings in terms of preference and satisfaction than previously used DPI devices. In order to improve asthma adherence strategies, patient preferences and device choice should be taken into account.

**Keywords:** patient satisfaction, adherence, inhaler devices, dry powder inhalers, asthma control, clinical outcomes

# Plain Language Summary

Treatment of chronic diseases such as asthma has traditionally been associated with poor long-term adherence. Lack of adherence has adverse consequences on asthma control, which in turn affects quality of life. Effectiveness of treatment for chronic conditions depends widely on patient behavior and adherence. Therefore, doctors are always looking for new strategies to improve adherence and acceptance of treatments through patient education. Appropriate choice of dry powder inhaler is essential if we are to ensure control of asthma.

The DPI PREFER study was designed to compare patient preference for the Easyhaler device in comparison to other asthma devices containing a combination of the same drugs. To accomplish this, ease of training and ease of use of the Easyhaler device were assessed using rapid evaluation procedures similar to clinical practice conditions.

Correspondence: Francisco Javier Alvarez-Gutiérrez Unidad de Asma, Hospital Universitario Virgen del Rocio, Av. Manuel Siurot, S/n, Sevilla, 41013, Spain Email fjavieralvarez2008@gmail.com In our study, adult patients completed various questionnaires on ease of use, adherence, satisfaction, and preference for Easyhaler compared with other previously used inhaler devices. Easyhaler achieved better patient ratings in preference and satisfaction than other previously used dry powder inhalers. Our study also reinforces that patient preferences and device choice should be taken into account in order to improve patient adherence in asthma management.

#### Introduction

Long-term treatment of chronic diseases such as asthma has classically been associated with low adherence. Lack of adherence impairs control of asthma, in turn resulting in increased morbidity and mortality, poor quality of life, and increased use of healthcare resources. Although adherence is critical to clinical outcome, it is not maintained in the long term, <sup>1–5</sup> and, depending on the assessment method used, adherence in asthma patients has been reported to range from 16% to 43%. <sup>4–6</sup>

The factors underlying lack of adherence to asthma treatment include patient education/training, ease of use of the inhaler device, patient satisfaction, age, and adverse effects of medication. Poor adherence to pharmacological treatment of asthma has adverse consequences for disease control.<sup>7–10</sup>

The effectiveness of treatment of chronic conditions depends largely on patient behavior and adherence. Guidelines recommend that when choosing a specific intervention program, physicians should take into consideration factors such as proper use of an inhaler device and patient preference. 10–12

Specialists who treat affected patients on a daily basis are very aware of these issues. Therefore, expert groups and societies are always investigating new strategies to improve adherence and acceptance of treatment through patient education. 13–17

Patient preference for inhaler devices has been considered a necessary part of strategies to ensure more accurate device selection. The correct choice of device can improve patient satisfaction with treatment, reduce errors in inhalation technique, and increase adherence, leading to more favorable clinical outcomes.<sup>7–10,16–20</sup>

Recent studies such as ASCONA (Asthma Satisfaction, CONtrol and Adherence) assessed the impact of patient satisfaction with an inhaler device on adherence and health outcomes. The results of this observational study reinforced the relevance of patient satisfaction with the inhaler as a critical factor influencing adherence, proper inhalation technique, and better disease control as the final outcome.

Irrespective of the medication received, patient satisfaction with the inhaler device was related to improved adherence and better control of asthma.<sup>19</sup>

A post hoc analysis of a homogeneous subpopulation of the ASCONA study revealed Easyhaler<sup>®</sup> (Orion Corporation, Finland) to be the device with the highest score for patient satisfaction compared with various dry powder inhaler (DPI) devices.<sup>20</sup>

Many patients do not use inhalers properly, probably because of improper choice of device, intrinsic features of the inhaler, or insufficient training in inhaler technique. Inadequate inhaler technique correlates with both poor symptom control and more frequent asthma exacerbations. The convenience and accuracy of the Easyhaler device has been demonstrated in various conditions and clinical settings and in comparison with other DPI devices. <sup>13–20</sup>

The DPI PREFER (Dry Powder Inhaler PREFerence versus Easyhaler in Referred asthmatic patients) study was designed and carried out to compare patient preference for the Easyhaler device with that of other DPI devices containing a combination of agents from the same pharmacological family (inhaled corticosteroids and long-acting beta-2 agonists [ICS and LABA]). In order to accomplish this, patient satisfaction, adherence, ease of training, and ease of use of the Easyhaler device were assessed using rapid evaluation procedures that mimic clinical practice conditions.

## **Methods**

# **Objectives**

The primary objective of the DPI PREFER study was to assess preference and satisfaction with the Easyhaler in a population of patients previously treated with a variety of DPIs.

The secondary objectives were to compare the ease of training in the use of Easyhaler with that of other DPIs and to estimate patient satisfaction and ease-of-use of inhaler devices.

# Study Design

DPI PREFER was a multicenter, non-interventional, non-drug-related, cross-sectional, single-visit, observational study in adult patients with persistent asthma referred to specialized care.

## Inclusion and Exclusion Criteria

In order to be included in the study, patients had to be adult outpatients (≥18 years), with bronchial persistent

asthma who had been referred for the first time to specialist care (allergist or pulmonologist). They also had to be have been receiving an inhaled ICS/LABA combination through a DPI device (other than Easyhaler) for at least 3 months.

We excluded patients with disabling conditions or cognitive impairment that might, in the researchers' opinion, affect their participation in the study and patients who did not sign the informed consent document.

#### Assessments

All patient data were collected at a single visit. After checking clinical baseline data, patients filled in questionnaires on asthma control and satisfaction with and adherence to their inhaler. Patients were then trained in the use of Easyhaler and assessed for ease of use and device preferences. All of the instruments were validated in Spanish.

Patient satisfaction with the current inhaler was assessed using an adapted Feeling of Satisfaction with Inhaler questionnaire (FSI-10), 17-19 a self-completed instrument for obtaining patient opinions regarding the portability and usability of inhaler devices, irrespective of the drug administered. Each of the questions has 5 response options on a Likert scale from poorer to greater ease of use (scored 1 to 5, respectively). 16,18-20 To preserve comparability with the new device, 2 questions regarding long-term use were removed. The adapted FSI-10 comprises 7 questions, each with 5 possible responses on a 5-point Likert scale (very, fairly, somewhat, not very, hardly at all) scored from 5 to 1, respectively. The total FSI-10 Score was calculated as the parametric sum of all scores producing a whole number value in which a higher score represents greater satisfaction than a lower score.

Adherence was evaluated using the 12-item Test of Adherence to Inhalers (TAI), <sup>17</sup> which consists of 10 items in the patient domain, plus a further 2 items in the physician domain. In these 2 items, the researcher evaluates the patient's understanding of the dosing regimen (dose and frequency) and performance of inhalation technique without critical errors. <sup>17</sup> Each of the 10 self-completed items is scored from 1 to 5, where 1 is the worst possible score and 5 is the best possible score. Results range from 10 to 50 points and identify the level of adherence as poor (45 or fewer points), intermediate (46–49 points), or high (50 points). In addition, the 2 items completed by the researcher can identify 3 patterns of non-adherent behavior: erratic, deliberate, and unwitting.

A single patient may be classified as having more than 1 type of non-adherent behavior. 17-20

Patients also completed the 4-item Morisky-Green questionnaire on adherence, which includes 4 questions with yes/no response options and is scored from 0 to 4. The tool reflects 3 levels of adherence on the basis of this score: high (0 points), intermediate (1 to 2 points), and low (3 to 4 points). <sup>21,22</sup>

Asthma control was investigated using the GINA questionnaire, which enables a simple retrospective assessment that can easily and quickly screen out patients with poor control. 10,23-25

## Easyhaler Training

Included patients were trained in using the new Easyhaler device. The researcher then checked the patient's inhalation technique with both devices (Easyhaler and current DPI) and completed a training evaluation form. Finally, the patient completed a 4-item self-perception questionnaire to evaluate his/her preference with each of the devices.

## Sample

A total of 500 patients were considered necessary to carry out the study. The sample was calculated based on previous FSI-10 scores attained by Easyhaler and other DPIs in the ASCONA study. The sample required the participation of 100 researchers to recruit 5 consecutive referred patients with bronchial asthma receiving treatment with ICS/LABA through a DPI.

## Statistical Analysis

The statistical analysis was performed using SPSS 25.0 (IBM SPSS Statistics for Windows, Version 25.0, IBM Corp., Armonk, NY, USA). Statistical tests, tables, and charts were based only on the number of valid cases.

Descriptive statistics were applied for all data. Categorical variables were presented as frequencies and percentages. Quantitative variables (continuous or ordinal) were analyzed using measures of central tendency (mean, median) and dispersion (standard deviation, maximum and minimum).

Inferences were analyzed using Pearson's chi-square test for categorical variables and through ANOVA testing for continuous variables. A multiple logistic regression model (stepwise forward method) was then applied to assess the independence of the factors detected.

A statistical analysis plan was established to achieve the objectives of the study.

## **Ethics**

DPI PREFER was sponsored by the Spanish Society of Pulmonology and Thoracic Surgery (SEPAR) as a non-interventional study in which the exposure investigated is not a medication. Participation in DPI PREFER did not imply interference with or modification of standard therapeutic practices. Given the nature of the study, epidemiological data were recorded only during the medical visit. Before inclusion, the researcher provided the patient with detailed information on the study and obtained his/her written informed consent.

The protocol and all study materials were assessed and approved by the Clinical Research Ethics Committee (CREC) of Hospital Virgen de la Macarena, Seville, Spain. The study was implemented in accordance with the principles adopted by the 18th World Medical Assembly (Helsinki, 1964) and the amendments of the 64th General Assembly (Fortaleza, 2013) and was carried out according to Good Clinical Practice and ethics codes.

All data were obtained during a single medical visit and treated confidentially, in accordance with Spanish data protection laws.

The study was funded by a non-restrictive grant from Orion Corporate (Espoo, Finland)

## **Results**

A total of 502 patients were recruited between November 2019 and March 2020. All 502 patients met the inclusion criteria, and of these, 485 (96.6%) completed all the questionnaires on the patient case report form. Ninety medical centers and hospitals throughout Spain participated in the study.

Patient demographic and clinical characteristics are shown in Table 1.

The most commonly reported comorbidities were hypertension, nasal polyposis, allergic rhinitis, and obstructive sleep apnea.

The evaluation of current treatment showed that 486 patients (96.2%) were receiving inhaled maintenance therapy, 366 (72.9%) inhaler relief therapy, and 244 (48.6%) oral treatment. The DPIs included in this comparison were Turbuhaler<sup>®</sup> (AstraZeneca, UK [173 patients]), Ellipta<sup>®</sup> (GlaxoSmithKline, UK [95 patients]), NEXThaler<sup>®</sup> (Chiesi Farmaceutici SpA, Italy [85 patients]), Accuhaler<sup>®</sup> (GlaxoSmithKline, UK [55 patients]),

Table I Demographic and Clinical Characteristics (N=502)

Characteristics	
Sex (female) n (%)	317 (63.1)
Age (yrs, mean ± SD)	50.2±16.2
Age at onset of asthma (yrs, mean ± SD)	34.4±19.1
Age at initiation of asthma therapy (n=494) (yrs, mean $\pm$ SD)	39.9±17.2
Lung function, n (%)	
FEV ≥80% predicted and PEF ≥80% personal best	293 (58.4)
FEV <80% predicted or PEF <80% personal best	159 (31.7)
FEV <60% predicted	48 (9.6)
Unknown	2 (0.4)
Smoking, n (%)	
Never smoker	300 (59.8)
Former smoker	143 (28.5)
Current smoker	57 (11.4)
Unknown	2 (0.4)
Patients with comorbidities, n (%)	244(48.6)

Abbreviations: FEV, forced expiratory volume; PEF, peak expiratory flow.

Spiromax<sup>®</sup> (Teva Pharmaceutical Industries, Israel [30 patients]), and other DPIs (48 patients).

According the GINA 2019 criteria, 29.9% of the total sample had mild persistent asthma, 51.6% had moderate persistent asthma, and 18.5% had severe persistent asthma. No patients had intermittent asthma; this finding was as expected because of the exclusion criteria. In addition, asthma was controlled in 184 (36.7%) patients and partially controlled or uncontrolled in 192 (38.2%) and 123 (25.1%) of patients, respectively. When the last 2 categories were considered together, asthma was partly or poorly controlled in 63.3% of patients.

According to the Morisky-Green questionnaire, 181 (36.1%) patients adhered to treatment.

The results of the Test of Adherence to Inhalers (TAI) in the 485 patients who completed the test, showed that adherence was poor in 211 patients (43.5%), intermediate in 167 (34.4%), and good in 107 (22.1%). According to the physician's evaluation in the last 2 questions of the test, 91% of patients knew or remembered the pattern (dose and frequency) that was prescribed, and 79.3% did not make critical mistakes related to inhalation technique. The type of non-adherent behavior was identified as erratic in 25.3%, deliberate in 43.6%, and unwitting in 74.7%; it must be remembered that non-adherent patients may be classified in more than 1 of these 3 categories.

After training patients in the use of a new Easyhaler device, researchers checked the patient's

Table 2 Easyhaler Training Evaluation, n (%)

	Total (n=502)
Ease of training in the use of the Easyhaler device	
Very	302 (60.2)
Fairly	174 (34.7)
Somewhat	20 (4.0)
Not very	4 (0.8)
Hardly at all	2 (0.4)
Training time	
<5 min	423 (84.3)
5–10 min	74 (14.7)
10–20 min	5 (1.0)
>20 min	0
Need to repeat instructions (yes)	153 (30.5)
Number of repetitions (more than once)	78 (15.5)
Easyhaler instructions are clear and easy to	478 (95.2)
understand (yes)	
Difficulty using Easyhaler device (yes)	54 (10.8)
Critical mistakes in the Easyhaler inhalation	23 (4.6)
technique *	

**Notes:** \*Critical mistakes with Easyhaler: The patient does not open the device, does not shake and prepare the device properly before inhaling, does not hold the device in the upright position with the mouthpiece down, exhales into the device, does not inhale as fully as possible, does not hold breath after inhaling.

inhalation technique and ease of training with the currently used device and Easyhaler. The evaluation of training was completed by 502 patients. Training in the use of Easyhaler was considered very easy or fairly easy by 95.9% of patients; 10.8% of participants reported difficulty using Easyhaler, and critical mistakes were reported in only 4.6% (Table 2).

The primary objective of the study was evaluated through the results of the adapted FSI-10 test in 485 valid cases (patients who completed the questionnaire). The results are shown as a qualitative evaluation (Table 3) and as a quantitative evaluation (Table 4). Satisfaction with Easyhaler was significantly higher than with the previous inhaler ( $31.8 \pm 3.24$  points vs  $29.12 \pm 5.15$  points).

Age, sex, lung function, asthma severity, asthma control, inhaler adherence, and inhaler type were evaluated for their effect on the patient's satisfaction with the inhaler. Low satisfaction with previous inhalers was significantly associated with poor asthma control and poor adherence, although mostly with inhaler type (Table 5).

Finally, patient device preference was evaluated using a self-reported questionnaire. On the whole, 84.1% of patients preferred Easyhaler, 38.4% of patients preferred

**Table 3** FSI-10-Based Qualitative Evaluation of Easyhaler Training (n=485)

	Previous Inhaler, n (%)	Easyhaler, n (%)	P value
I. Was it easy to learn how to use the inhaler?			
Very	189 (39.0)	297 (61.2)	<0.001
Fairly Somewhat	183 (37.7) 74 (15.3)	164 (33.8) 18 (3.7)	
Not very	30 (6.2)	4 (0.8)	
Hardly at all	9 (1.8)	2 (0.4)	
2. Was it easy to prepare			
the inhaler for use?			
Very	230 (47.4)	296 (61.0)	<0.001
Fairly	170 (35.1)	169 (34.8)	
Somewhat	51 (10.5)	15 (3.1)	
Not very	21 (4.3)	2 (0.4)	
Hardly at all	13 (2.7)	3 (0.6)	
3. Was the inhaler easy to use?			
Very	242 (49.9)	300 (61.9)	<0.001
Fairly	170 (35.1)	169 (34.8)	10.001
Somewhat	50 (10.3)	13 (2.7)	
Not very	17 (3.5)	2 (0.4)	
Hardly at all	6 (1.2)	I (0.2)	
4. Did the inhaler fit your			
lips comfortably?			
Very	213 (43.9)	280 (57.7)	<0.001
Fairly	179 (36.9)	183 (37.7)	
Somewhat	59 (12.2)	17 (3.5)	
Not very	26 (5.4)	3 (0.6)	
Hardly at all	8 (1.6)	2 (0.4)	
5. Was it easy to use the			
inhaler in terms of size and			
weight?	221 (45.4)	340 (73.0)	<0.001
Very	221 (45.6)	349 (72.0)	<0.001
Fairly Somewhat	189 (39.0) 46 (9.5)	128 (26.4) 6 (1.2)	
Not very	46 (9.5) 22 (4.5)	0 (1.2)	
Hardly at all	7 (1.4)	2 (0.4)	
6. After using the inhaler, do		•	
you feel that you used it			
correctly?			
Very	174 (35.9)	253 (52.2)	<0.001
Fairly	200 (41.2)	193 (39.8)	
Somewhat	67 (13.8)	28 (5.8)	
Not very	36 (7.4)	6 (1.2)	
Hardly at all	8 (1.6)	5 (1.0)	

(Continued)

Table 3 (Continued).

	Previous Inhaler, n (%)	Easyhaler, n (%)	P value
7. Overall, considering your answers to the above questions, were you satisfied with the inhaler?  Very Fairly Somewhat Not very Hardly at all	196 (40.4) 204 (42.1) 56 (11.5) 25 (5.2) 4 (0.8)	265 (54.6) 197 (40.6) 20 (4.1) 3 (0.6) 0	<0.001

Abbreviation: FSI-10, 10-item Feeling of Satisfaction with Inhaler.

Table 4 FSI-10 Parametric Quantitative Evaluation of Satisfaction with Previous or New Inhaler (n=485)

	Previous Inhaler	Easyhaler	P value *		
I. Was it easy to learn how to use the inhaler?	4.06±0.98	4.55±0.65	<0.001		
2. Was it easy to prepare the inhaler for use?	4.20±0.98	4.55±0.64	<0.001		
3 .Was it easy to use the inhaler?	4.29±0.88	4.58±0.59	<0.001		
4. Did the inhaler fit your lips comfortably?	4.16±0.95	4.52±0.64	<0.001		
5. Was the inhaler easy to use the inhaler in terms of size and weight?	4.23±0.90	4.69±0.54	<0.001		
6. After using the inhaler, do you feel that you used it correctly?	4.02±0.97	4.41±0.75	<0.001		
7. Overall, considering your answers to the above questions, were you satisfied with the inhaler?	4.16±0.88	4.49±0.61	<0.001		
TOTAL FSI-10 SCORE	29.12±5.15	31.8±3.24	<0.001		

Note: \*Statistically significant values (paired-samples t test).

Easyhaler exclusively, while preference was similar for both devices in 45.8% of patients. Only 15.3% of patients exclusively preferred the previous device (Figure 1).

Preference for Easyhaler or the previous inhaler was analyzed according to the clinical categories used in the study. Patients reported their preference for the new device (Easyhaler) or for the previous inhaler or reported an equal

preference for both devices. Table 6 shows preferences in relation to the study clinical categories.

Factors that were significant in the univariate analysis of preference were included in a multiple regression analysis. The only independent predictors of device preference were the FSI-10 score and TAI score. The FSI-10 score for the previous inhaler and the TAI score significantly favored preference for the previous inhaler. Similarly, the FSI-10 score for Easyhaler strongly predicts preference for the new device, with an odds ratio of 1.79. A forest plot from the multivariate logistic regression analysis can be seen in Figure 2.

#### Discussion

Regardless of the inhaled medication, patient preference for a specific inhaler device is crucial in achieving longterm control of asthma. Choosing the right device increases adherence, reduces inhalation technique mistakes, and improves patient satisfaction. 1-6 Giner et al 16 conducted a study to evaluate preferences between 3 DPIs, (Accuhaler, Easyhaler, and Turbuhaler) in 30 adult patients with stable asthma. Patients were shown how to use each of the devices and were randomized to begin using them in different orders. Preference was assessed based on 9 features of the DPIs. Easyhaler was the first choice for 53% of patients, while Turbuhaler and Accuhaler were preferred by 27% and 20%, respectively.

Unfortunately, studies based on short-term use of various devices are not suitable in real life. Therefore, the present study used a short training course as a tool to challenge patients' preference with respect to their previous DPI device.

Available evidence indicates that Easyhaler is an appropriate DPI for testing this hypothesis. A recent review found that Easyhaler received high patient preference ratings and may be considered one of the most convenient inhalers for daily use in patients with asthma or COPD.<sup>30</sup> Similarly, a recent assessment of DPI features that may affect use, patient satisfaction, and clinical benefit concluded that the design features of Easyhaler make it one of the most convenient devices for daily use in patients with asthma or COPD.<sup>31</sup>

Our study showed that more participants preferred Easyhaler to other commonly used inhaler devices (Accuhaler, Turbuhaler, Spiromax, Ellipta, NEXThaler). Preference for Easyhaler was reported by 84.1% of patients, while 61.1% preferred their previous inhaler. Preference rates were the same for both devices

Table 5 Factors Influencing the Test of Satisfaction (FSI-10 Questionnaire)

	n	Previous Inha	ler	Easyhaler Dev	ice
			Qualitative	e Variables	
		Median (p25/p75)	р	Median (p25/p75)	р
Lung function					
FEV ≥80% predicted	288	29.7±4.8	0.006	32.0±3.2	0.023
FEV <80% predicted	195	28.2±5.5		31.5±3.2	
Adherence level (TAI)					
Low	211	28.0±5.2	<0.001	31.8±3.5	0.121
Moderate	167	30.0±4.4		31.9±3.0	
High	107	30.1±5.6		31.7±3.3	
Asthma severity					
Mild	146	30 (26/34)	0.882	32 (30/34)	0.374
Moderate	248	29 (26/34)		33 (30/35)	
Severe	91	31 (28/34)		32 (29/35)	
Asthma Control (GINA 2019 criteria)					
Good control	184	31 (28/35)	<0.001	33 (29/35)	0.654
Partial/poor control	301	29 (25/33)		32 (30/34)	
Maintenance inhaler					
Turbuhaler	165	29 (25/33)	<0.001	33 (30/35)	0.645
Ellipta	92	31 (27.5/34)		32 (29/34)	
Nexthaler	82	31 (29/34)		33 (29/35)	
Accuhaler	51	27 (24/30)		33 (31/35)	
Spiromax	30	30 (26/34)		32 (30/34)	
Other	45	31 (27/35)		33 (30.5/35)	

Abbreviations: FEV, forced expiratory volume; TAI, Test of Adherence to Inhalers.

(previous and Easyhaler) in 45.8% of patients. Exclusive preference for Easyhaler was reported by 38.4% of patients, while only 15.3% of participants preferred exclusively the previous device.

We also evaluated patient satisfaction using the FSI-10 questionnaire, which has proven useful for assessing the

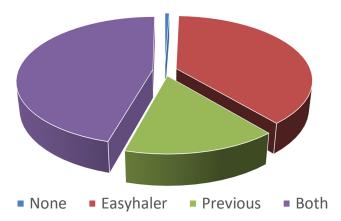


Figure 1 Device preference according to a self-reported questionnaire (n = 485).

degree of satisfaction with inhalation devices among patients with asthma. The instrument is comprehensive, easy to understand, and can identify differences in patient satisfaction with various inhalers.  $^{17-20}$  Consistent with previous findings, our results indicate that satisfaction is greater with Easyhaler than with the previous inhaler (31.8  $\pm$  3.24 points vs 29.12  $\pm$  5.15 points).

Valero et al $^{20}$  compared patient satisfaction with 3 DPIs (Easyhaler, Turbuhaler, and Accuhaler) in a post hoc analysis of a homogeneous subpopulation (n=328) from the ASCONA study. Patients with moderate to severe asthma were paired according to age, sex, and severity. Patient satisfaction with the device was assessed using the FSI-10 questionnaire. Scores for Easyhaler were significantly better for individual FSI-10 items such as learning how to use the device, inhaler preparation, inhaler use, weight and size, and portability. Satisfaction with the inhaler was statistically significantly greater for Easyhaler (43.8  $\pm$  7.1) than for Turbuhaler or Accuhaler (41.3  $\pm$  7.6; p < 0.01).

**Table 6** Patient Preference According to the Clinical Categories Used in the Study (N=482), n (%)

	Previous Inhaler Preferred	Easyhaler Preferred	р
N	74 (15.4)	186 (38.6)	
Lung function FEV ≥80% predicted FEV <80% predicted	52 (18.1) 22 (11.5)	99 (34.4) 87 (45.3)	0.013
Asthma control Good control Partial/poor control	36 (19.6) 38 (12.8)	55 (29.9) 131 (44.0)	0.004
Maintenance inhaler Turbuhaler Ellipta Nexthaler Accuhaler Spiromax Otros	20 (12.1) 18 (19.6) 21 (25.6) 2 (3.9) 5 (16.7) 6 (13.3)	79 (47.9) 24 (26.1) 19 (23.2) 30 (58.8) 12 (40.0) 13 (28.9)	<0.001
Quantitative variables FSI score of previous inhaler FSI score of Easyhaler Adherence (TAI score) with previous inhaler	32 (28/34) 29 (28/32) 47.5 (45/50)	27 (23/31) 33 (31/35) 45.5 (38/48)	<0.001 <0.001 <0.001

In their real-life multicenter, noncontrolled study, Gálffy et al<sup>29</sup> assessed patients' handling, ease of learning, and satisfaction with the Easyhaler device in 1016 asthma or COPD patients attending respiratory clinics. Patients

found Easyhaler easy to learn and use, and satisfaction with the device was very high.

The level of patient satisfaction with the inhaler device has a positive influence on asthma control through its association with higher adherence. 13 We found the same significant association between satisfaction with the previous inhaler and adherence, asthma control, and even pulmonary function (Table 5). The association with satisfaction was not found for Easyhaler, since the assessment was isolated and Easyhaler was not the patient's usual inhaler. The level of adherence in our study was similar to that found in other asthma inhaler trials. 13–20

Regarding device preferences, we found similar associations (Table 6), including FSI-10 scores. Remarkably, when all these factors were included in the multivariate logistic regression analysis, the predictors of device preference were the satisfaction score (FSI-10) and, albeit only marginally, the adherence score (TAI). The results of our multivariate analysis confirm the association between Easyhaler and high rates of user satisfaction. In a 12-week, real-world, multicenter, open-label study conducted in 398 and 563 adult patients with asthma and COPD, respectively, significant increases in patient satisfaction were also reported with Easyhaler compared with previously used inhalers. <sup>14</sup>

These results point to a short training session as being a suitable means for challenging patients' preference for their current DPI inhaler. Additionally, the FSI-10 test could be the most valuable means of predicting changes in preference.

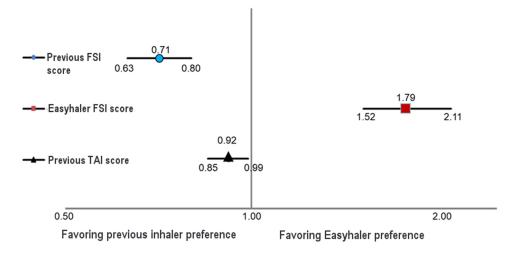


Figure 2 Forest plot of the multivariate logistic regression analysis showing odds ratios with 95% confidence intervals of the impact on the patient's preference of satisfaction score (FSI) for the previous inhaler, the FSI-10 score for the Easyhaler, and the adherence score (TAI) for the previous inhaler.

Abbreviation: TAI, Test of Adherence to inhalers.

Our study is limited in that its cross-sectional design enables it to provide only a limited picture of patient satisfaction at a particular timepoint; this picture is likely to change over time because of the chronic nature of asthma. However, the patients included in the study had at least 3 months' experience with their maintenance treatment and were therefore able to assess its suitability. Similarly, our finding of fewer critical mistakes in the Easyhaler technique could be influenced by the fact that the evaluation was performed immediately after the training session, thus likely minimizing the possibility of errors. Since inhaler errors may develop over time, the relevance of these findings for the real-life, long-term use of the devices remains unclear.

In addition, our study was observational. Since a blinded study is not feasible for assessment of device preferences, a noncontrolled evaluation of inhaler devices without random allocation always has the potential for bias. The need for homogeneous patient populations implies that randomized controlled trials would not be representative of the real-world asthma population.

#### **Conclusion**

In the present study, Easyhaler achieved better patient ratings in preference and satisfaction than the DPI device previously used by the patient. In order to improve asthma adherence strategies, patient preferences and device choice should be taken into account.

In addition, patient preference may change after some time of regular usage, therefore, follow-up studies will be needed to clarify the actual clinical benefit of the expressed preferences.

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