Impact of patient satisfaction with his or her inhaler on adherence and asthma control

Vicente Plaza, M.D., Ph.D.,¹ Jordi Giner, Ms.C., R.N., Ph.D.,¹ Myriam Calle, M.D., Ph.D.,² Paula Ryttilä, M.D., Ph.D.,³ Carlos Campo, M.D., Ph.D.,⁴ Paula Ribó, M.D.,⁵ and Antonio Valero, M.D., Ph.D.,⁵ on behalf of the ASCONA study investigators.

ABSTRACT

Background: Asthma guidelines recommend considering patient preferences for inhaler choice. However, few studies have assessed the impact of patient satisfaction with an inhaler on adherence and health outcomes.

Objective: To assess the impact of patient satisfaction with an inhaler on adherence and health outcomes in asthma.

Methods: In a cross-sectional, observational, multicenter study, 778 patients with moderate or severe asthma and who were treated with maintenance inhalers completed a number of scales and questionnaires: the Feeling of Satisfaction with Inhaler (FSI-10) questionnaire, the Treatment Satisfaction Questionnaire for Medication, the Test of Adherence to Inhalers (TAI), the Morisky-Green questionnaire, and the Asthma Control Test (ACT).

Results: The study population was categorized according to a median FSI-10 score as high (49.4%) and low (50.6%) satisfaction with their inhaler. Logistic regression analysis showed that high specific satisfaction with an inhaler was associated with the younger age group (odds ratio [OR] 0.976 [95% confidence interval {CI} 0.965–0.987]); male gender (OR 1.725 [95% CI 1.187–2.507]); controlled asthma: ACT score ≥ 20 (OR 1.664 [95% CI 1.133–2.445]); high general satisfaction with treatment (OR 4.861 [95% CI 3.335–7.085]); high adherence to inhaler: TAI score ≥ 46 (OR 1.546 [95% CI 1.025–2.332]); nonsevere asthma (OR 1.056 [95% CI 0.648–1.721]); and no trouble with inhaler use (OR 0.401 [95% CI 0.174–0.922]).

Conclusion: High patient satisfaction with an inhaler, irrespective of received medication, was related to adherence and asthma control. Our results pointed out the relevance of inhaler choice in inhaled therapy; these results could be useful for designing new strategies targeted to increase adherence in patients with asthma.

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Guidelines on asthma management highlight the relevance of adherence to maintenance inhaled therapy.^{1,2} Nonadherence results in poor asthma control, which thus increases morbidity and mortality,^{3,4} and impairs quality of life.⁵ However, up to 50% of patients with asthma are nonadherent.⁶ This percent-

age could be higher. In a recent study, only 16% of the patients were adherent according to the Morisky-Green questionnaire, and only 9% of patients were considered adherent according to data from pharmacy offices.⁷

Factors related to inhaler devices have been associated with adherence to inhaled therapy in asthma, including correct inhalation technique⁸ and ease of use.⁹ Asthma guidelines recommend considering patient preferences for inhaler choice^{1,2} and that use of an inhaler preferred by the patient can help to achieve asthma control.¹⁰ Another factor is patient-specific satisfaction with an inhaler, which affects adherence to asthma therapy.^{11,12} Moreover, a relationship between patient satisfaction and adherence was found in other chronic diseases,¹³ which emphasizes the importance of taking into account patient preferences when achieving adherence to long-term therapies.¹⁴ For all these reasons, we designed and carried out a study with the main objective to explore the impact on adherence and asthma control of patient satisfaction with an inhaler.

METHODS

The Asthma Satisfaction, Control and Adherence (ASCONA) study was a cross-sectional, observational study conducted in 59 hospitals across Spain. The

From the ¹Department of Respiratory Medicine, Hospital de la Santa Creu i Sant Pau, Institut d'Investigació Biomèdica Sant Pau, Centro de Investigaciones Biomédicas en Red de Enfermedades Respiratorias, Universitat Autònoma de Barcelona, Barcelona, Spain, ²Pulmonary Department, Hospital Clínico San Carlos, Department of Medicine, Faculty of Medicine, University Complutense of Madrid, Institute of Biomedical Research, Hospital Clínico San Carlos, Madrid, Spain, ³Orion Corporation Orion Pharma, Espoo, Finland, ⁴Orion Pharma, Madrid, Spain, and ⁵Servicio de Neumología y Alergia, Hospital Clínic, Institut d'Investigacions Biomèdiques August Pi i Sunyer, Centro de Investigaciones Biomédicas en Red de Enfermedades Respiratorias, Barcelona, Spain

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Address correspondence to Vicente Plaza, M.D., Ph.D., Servei de Pneumologia, Hospital de la Santa Creu i Sant Pau, Calle Mas Casanovas, 90, 08041, Barcelona, Spain

E-mail address: vplaza@santpau.cat

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study's scientific committee selected the participating physicians according to an appropriate geographic distribution and the involvement of centers with different levels of care. Seventy-three investigators participated in the study: 37 (50.7%) were specialists in allergy and 36 (49.3%) were specialists in pulmonology.

Eligibility criteria for patients was age ≥ 18 years, physician-confirmed asthma diagnosis, moderate or severe asthma according to the Global Initiative for Asthma guidelines,¹ and continuing therapy with the same inhaler for at least 3 months before inclusion in the study. Exclusion criteria were disabling comorbidities and/or cognitive impairment according to the investigator. The participating physicians consecutively selected all patients who fulfilled the inclusion criteria. The sample size was estimated at 724 patients (alpha error of 0.05 and power of 80%) and then was increased to 800 patients to cover for possible losses. The study was carried out in accordance with the 1991 International Guidelines for Ethical Review of Epidemiological Studies, and compiled with the updated version of the Declaration of Helsinki and Order SAS/3470/2009. The Clinical Research Ethics Committee of the Hospital Clinic from Barcelona (Spain) (code OR-IN-OB-2014) approved the study protocol. All the patients gave their written informed consent.

In a single visit, the patients filled out an electronic data collection form that included sociodemographic data, current therapy, and several questionnaires and tests. Patient satisfaction with his or her current inhaler was assessed with the specific Feeling of Satisfaction with Inhaler (FSI-10) questionnaire.¹⁵ General patient satisfaction with treatment was also assessed with the Treatment Satisfaction Questionnaire for Medication (TSQM).^{16,17} Adherence was evaluated with the Test of Adherence to Inhalers (TAI)¹⁸ and the four-item Morisky-Green questionnaire.^{19,20} Also, the patients completed the Asthma Control Test (ACT; OptumInsight Life Sciences, Inc., Lincoln, RI).²¹⁻²³ All these instruments are validated in Spanish.

The FSI-10 is a self-completed questionnaire that assesses the portability and usability of inhalers, irrespective of the administered drug therapy. It consists of 10 questions, each with five options in a Likert scale scored from 5 (very) to 1 (hardly at all), and a maximum total score of 50 (Supplemental Table S1).¹⁵ The TAI assesses the adherence to inhaled therapy and consists of two complementary questionnaires: the 10-item TAI and the 12-item TAI (Supplemental Table S2). The 10-item TAI (self-completed by the patient) identifies patients with poor adherence and the level of adherence. Each item ranges from 1 (lowest adherence) to 5 (highest adherence) points. The questionnaire categorizes adherence as good (50 points), intermediate (46–49 points), and poor (≤ 45 points).

In turn, the 12-item TAI orients the pattern of non-adherence and consists of the 10 items in the patient's domain, plus another 2 items that are in the domain of health care professionals: item 11 (knowledge of the dosing regimen by the patient) and item 12 (performance of inhalation technique without critical errors). These two items score as 1 (bad) or 2 (good) points. The 12-item TAI identifies three patterns of nonadherence: erratic (total score of items 1 to 5, ≤ 23 points), deliberate (total score of items 6 to 10, ≤ 23 points), and unwitting (total score of items 11 and 12, ≤ 3 points). Patients can show different patterns of nonadherence simultaneously.¹⁸ Participation was voluntary and anonymous, and no personal data were recorded.

Statistical Analysis

The main outcome measures included the mean scores of the FSI-10, TSQM, TAI, Morisky-Green questionnaire, and ACT as well as the percentage of patients with controlled asthma according to the ACT. The main validation variables were satisfaction with an inhaler, satisfaction with the medication, adherence to using the inhaler, ease of use of the inhaler, asthma severity, and asthma control. We performed a descriptive statistical analysis by using the number of valid cases: mean $\pm$ standard deviation and range for continuous variables, and percentage for categorical variables. Likewise, we considered only the number of valid cases in all tables and figures. Furthermore, we created dichotomous variables of FSI-10, TSQM, and ACT by using the median of global score for each questionnaire as cutoff points.

We used a single factor analysis of variance test for group comparisons, the Mann-Whitney U test or Kruskal-Wallis test for continuous dependent variables, and the χ^2 test for categorical dependent variables. We also used Pearson and Spearman correlations to assess the relationship among scale scores, and binary logistic regression to study the factors that affect dependent variables (satisfaction with their inhaler according to FSI-10 and asthma control according to the ACT). Moreover, we created tables of FSI-10 (Supplemental Table S3) and ACT (Supplemental Table S4) as dichotomous variables compared with the main study variables. All statistical analyses were performed with SPSS version 19.0 (SPSS Inc., Chicago, IL).

RESULTS

Nine hundred and thirty-three patients were recruited. However, 155 patients were not included because they were <18 years of age ($n = 12$) or did not have moderate or severe asthma (or these data were not included in their electronic data collection form) ($n = 143$). Thus, 778 patients were included in the study, mostly women (485 [64.4%]). Their sociodemo-

Table 1 Sociodemographic and clinical characteristics of the study population

Age, mean $\pm$ SD, y	46.76 $\pm$ 16.98
Age at asthma diagnosis	29.84 $\pm$ 19.00
Age at asthma therapy onset	31.61 $\pm$ 18.80
Asthma severity, no. (%)	
Moderate	635 (81.6)
Severe	143 (18.4)
Asthma control, no (%)	
Good (ACT score $\geq$ 20)	424 (57.7)
Poor (ACT score $<$ 20)	311 (42.3)
Current therapy, no. (%)	
Maintenance inhaled therapy	777 (99.9)
Oral therapy	160 (20.6)
Rescue inhaled therapy	331 (42.6)
Combination of therapies, no. (%)	
Only maintenance inhaled therapy	395 (50.8)
Maintenance inhaled therapy + rescue inhaler	223 (28.7)
Oral therapy + inhaled therapy (maintenance or maintenance and rescue)	159 (20.5)
Maintenance inhaler, no. (%)	
pMDI	68 (8.8)
DPI	707 (91.2)
Easyhaler	446 (63.1)
Turbuhaler	93 (13.2)
Diskus/Accuhaler	66 (9.4)
Ellipta	25 (3.5)
Spiromax	11 (1.6)
Nexthaler	7 (1.0)
Breezhaler	1 (0.1)
Unspecified	2 (0.3)

SD = Standard deviation; ACT = Asthma Control Test; pMDI = pressurized metered-dose inhaler; DPI = dry-powder inhaler; y= years.

graphic and clinical characteristics are presented in Table 1. All the patients were treated with a single inhaler for maintenance therapy, combined, or not, with rescue and/or oral therapy. The median of the FSI-10 global score was 43 on a scale from 10 (lowest satisfaction) to 50 (highest satisfaction). Thus, the FSI-10 dichotomous variable categorized 369 patients (49.4%) with high specific satisfaction with their current maintenance inhaler (FSI-10 score $\geq$ 43) and 378 patients (50.6%) with low specific satisfaction with their current maintenance inhaler (FSI-10 score $<$ 43), irrespective of received medication. The percentage of the patients with a high satisfaction with their inhaler was higher with dry powder inhalers (DPI) (51.6%) than with pressurized metered-dose inhalers (pMDI) (27.9%) ($p < 0.001$), also irrespective of drug therapy.

Specific satisfaction with an inhaler was statistically significantly higher in both men and younger patients, shown in Table 2, which also shows the comparison of variables related to adherence and satisfaction with treatment by the level of specific satisfaction with an inhaler. The patients with high specific satisfaction with an inhaler showed more adherence, with statistically significantly better scores in both the TAI and the Morisky-Green questionnaire compared with patients with a low specific satisfaction with their inhaler. All the patterns of nonadherence to inhaler according to TAI (erratic, deliberate, and unwitting) were less frequent in patients with high satisfaction with their inhaler, with statistically significant differences compared with the patients with low satisfaction with their inhaler. Similarly, patients with high satisfaction with their inhaler had higher general satisfaction with treatment, with statistically significantly better scores in all domains of the TSQM questionnaire (efficacy, lack of adverse events, convenience, and general satisfaction). The percentage of patients with low general satisfaction with medication was significantly lower in patients with high specific satisfaction with an inhaler.

The medians of the TSQM questionnaire dimensions were as follows: efficacy, 72.22; absence of adverse events, 100.00; convenience, 77.78; and general satisfaction, 76.39. Higher scores indicated higher satisfaction. We created a dichotomous variable of the TSQM score by using the median of general satisfaction (76) as the cutoff point. Accordingly, the patients were categorized as having high (54.7%) and low (45.3%) general satisfaction with their medication. In the patients with high satisfaction with their medication, poor adherence to their inhaler according to TAI was less frequent ($p < 0.001$), as were erratic, deliberate, and unwitting non-adherences ($p < 0.001$ for all).

Also shown in Table 2 are asthma variables of the patients distributed in high and low specific satisfaction with an inhaler. Satisfaction was statistically significantly higher in those with moderate asthma. Compared with the patients with low inhaler satisfaction, those with high satisfaction had statistically significantly fewer symptoms, activity limitation, and need for rescue medication as well as fewer exacerbations. In addition, the patients with high satisfaction with an inhaler were younger at asthma diagnosis and at therapy onset. There was no difference in the number of medications. Also, asthma control was statistically significantly better in patients with high specific satisfaction with their inhaler. In binary logistic regression analysis, the variables related with high specific satisfaction with an inhaler were younger age, male gender, high asthma control, high adherence, nonsevere asthma, and no trouble with an inhaler (Fig. 1 and Supplemental Table S3). In turn, the variables related with controlled asthma (ACT score $\geq$ 20) were male

Table 2 Age, gender, adherence, general satisfaction with medication, and asthma variables by level of specific satisfaction with an inhaler (FSI-10)

Variable	Specific Satisfaction with an Inhaler				Inference			
	High (FSI-10 ≥ 43)		Low (FSI-10 < 43)		Cohen's d	OR	95% CI	p
	Mean ± SD	%	Mean ± SD	%				
Sociodemographic data								
Age	43.63 ± 16.12		49.99 ± 17.36		0.38		0.23–0.53	<0.0001
Gender								
Male		56.7		43.3		1.56	1.15–2.12	0.0043
Female		45.6		54.4				
Adherence								
TAI								
Total score	47.30 ± 4.21		45.83 ± 5.37		0.3		0.15–0.45	0.0001
Poor or intermediate adherence (score ≤ 50)		57.0		64.7		1.38	1.02–1.86	0.0400
Erratic nonadherence score	23.05 ± 2.90		22.26 ± 3.35		0.25		0.1–0.4	0.0007
Erratic nonadherence		51.8		62.4		1.54	1.15–2.07	0.0045
Deliberate nonadherence score	24.23 ± 1.78		23.58 ± 2.37		0.31		0.16–0.46	<0.0001
Deliberate nonadherence		33.1		46.9		1.79	1.33–2.41	0.0001
Unwitting nonadherence score	3.94 ± 0.26		3.79 ± 0.51		0.37		0.22–0.52	<0.0001
Unwitting nonadherence		5.3		16.7		3.61	2.11–6.18	<0.0001
Morisky-Green								
Score	3.13 ± 0.98		2.93 ± 1.09		0.19		0.05–0.33	0.0077
Poor adherence (score < 4)		54.2		62.4		1.40	1.05–1.88	0.0256
General satisfaction with medication (TSQM)								
Efficacy	77.54 ± 19.82		65.99 ± 16.38		0.64		0.49–0.79	<0.0001
Lack of adverse events	97.74 ± 8.40		94.90 ± 13.34		0.25		0.1–0.4	0.0006
Convenience	84.23 ± 13.03		69.99 ± 12.85		1.1		0.95–1.25	<0.0001
General satisfaction	80.27 ± 14.80		67.72 ± 15.25		0.84		0.69–0.99	<0.0001
Low satisfaction		24.8		65.0		5.63	4.10–7.73	<0.0001
Asthma variables								
Age at diagnosis, y	27.21 ± 18.33		32.98 ± 19.43		0.31		0.16–0.46	<0.0001
Age at onset therapy, y	28.64 ± 18.50		34.94 ± 18.83		0.34		0.19–0.49	<0.0001
Current medications, no.	1.61 ± 0.71		1.67 ± 0.72		0.08		−0.06 to 0.22	0.2167
Severity								
Moderate		51.9		48.1		0.578	0.39–0.84	0.004
Severe		38.4		61.6				
GINA								
Poor control		8.2		22.8		3.29	2.11–5.13	<0.0001
Symptoms > 2 times a wk		27.9		44.9		2.11	1.55–2.86	<0.0001

Table 2 Continued

Variable	Specific Satisfaction with an Inhaler				Inference		
	High (FSI-10 $\geq$ 43)		Low (FSI-10 < 43)		Cohen's d	OR	95% CI
	Mean $\pm$ SD	%	Mean $\pm$ SD	%			
							<i>p</i>
Activity limitation		41.7		63.1		2.40	1.78–3.22
Night symptoms		31.3		52.0		2.38	1.76–3.21
Rescue β_2 -agonists		25.7		42.9		2.17	1.59–2.96
FEV ₁ < 80%		28.4		44.8		2.04	1.51–2.77
Exacerbations		41.6		60.5		2.15	1.60–2.88
ACT							<0.0001
Score							<0.0001
Poor controlled asthma (ACT <20)	20.79 $\pm$ 4.06	44.8	18.03 $\pm$ 4.53	69.4	0.64	2.79	0.49–0.79
							2.06–3.78
							<0.0001

FSI-10 = Feeling of Satisfaction with Inhaler-10; SD = standard deviation; OR = odds ratio; CI = confidence interval; TAI = Test of Adherence to Inhalers; TSQM = Treatment Satisfaction Questionnaire for Medication; GINA = Global Initiative for Asthma; FEV₁ = forced expiratory volume in the first second; ACT = Asthma Control Test; wk = week.

gender, high specific satisfaction with their inhaler, general satisfaction with their medication, and high adherence (Fig. 2 and Supplemental Table S4).

DISCUSSION

This real-world study emphasized the relevance of specific satisfaction with an inhaler for adherence and asthma control. Adherence was higher in patients with high specific inhaler satisfaction, irrespective of received medication. It also was higher in the patients with high general satisfaction with their treatment. A multivariate analysis showed that high asthma control, high general satisfaction with treatment, and high adherence to an inhaler favored high specific satisfaction with an inhaler, but trouble with inhaler use favored low satisfaction with the inhaler. Moreover, severe asthma was less common in patients with high satisfaction with their inhaler. Among these patients, symptoms were less frequent and asthma control was better in comparison with patients with low satisfaction with their inhaler. Furthermore, high satisfaction both specific to an inhaler and general to the treatment favored good asthma control, whereas trouble with inhaler use had the opposite effect.

General satisfaction with treatment is conceptually different from other types of patient-reported outcomes, such as symptom assessment or health-related quality of life.²⁴ General satisfaction with treatment is related to the experience with the medication and includes the process of taking the medication and the results achieved.²⁴ Satisfaction with a device, although it has been considered equivalent to general satisfaction with treatment,²⁵ it focuses on usability and portability of the device. Therefore, we chose a specific questionnaire, the FSI-10, to assess satisfaction with an inhaler. In addition, we used the TSQM to assess general satisfaction with treatment and, thus, to obtain an overview of patient satisfaction with inhaled therapy.

The impact of patients' satisfaction with their inhaler and medication on adherence and asthma control has not been extensively assessed. Two previous studies found a relationship between satisfaction with an inhaler and both adherence and asthma control.^{11,12} Small *et al.*¹¹ assessed satisfaction with their inhaler in 1345 patients with asthma who rated 13 device-specific attributes on a seven-point Likert scale as well as their overall satisfaction with their inhaler. Other instruments used were a physician-reported Likert scale for adherence, the European Quality of Life 5 dimensions scale, and the Jenkins Sleep Evaluation Questionnaire. The level of satisfaction with an inhaler is directly associated with adherence. Moreover, high satisfaction with an inhaler correlated with a better quality of life and fewer exacerbations, hospital visits, health-care visits, and sleep disturbances.¹¹

Figure 1. Binary logistic regression analysis by using specific satisfaction with the inhaler as the dependent variable (the Feeling of Satisfaction with Inhaler [FSI-10] questionnaire).

Figure 2. Binary logistic regression analysis: asthma control according to the Asthma Control Test (ACT) score as the dependent variable.

In turn, Price *et al.*¹² included 243 patients with asthma and used a modified version of the aforementioned satisfaction questionnaire with 12 inhaler-specific attributes rated on a five-point Likert scale. Adherence was assessed with the eight-item Morisky Medication Adherence Scale, whereas outcomes were evaluated with the ACT, Jenkins Sleep Evaluation Questionnaire, EQ 5D three-level version, and physician-reported number of exacerbations.¹² In this study, better clinical outcomes were significantly associated

with higher satisfaction with an inhaler and adherence, among other factors.¹²

Although a list of inhaler-specific attributes rated on a Likert scale is not a validated instrument,¹² it has been used in other studies. Chrystyn *et al.*²⁶ assessed the impact of patient satisfaction with an inhaler on adherence and outcomes in patients with chronic obstructive pulmonary disease ($n = 1443$). When using the same list of 13 attributes rated on a seven-point Likert scale as well as overall satisfaction with an in-

haler, they found an association between overall satisfaction with the inhaler and treatment adherence ($p < 0.001$). Moreover, higher adherence was associated with better health outcomes.²⁶ This result may show that satisfaction, adherence, and disease control in patients with chronic obstructive pulmonary disease are different from those in patients with asthma. Probably, specific satisfaction with an inhaler is more significant for better adherence and for disease control in patients with asthma.²⁷ Our study also found a relationship between satisfaction with an inhaler and both adherence and asthma control in almost a thousand patients. It was more comprehensive than other studies because we used multiple variables to cover as many factors as possible. Moreover, we used instruments that are validated, more precise, and specific for inhalers, such as the FSI-10 and TAI.

Satisfaction with their inhaler was higher in patients with DPIs. However, <10% of the patients used a pMDI as a maintenance inhaler. We cannot completely explain the reason of this imbalance between DPIs and pMDIs. DPIs were also the most used maintenance inhaler in >3730 patients with asthma.²⁸ In addition, a selection bias was unlikely because the participating physicians consecutively selected all the patients who fulfilled the inclusion criteria. In addition, satisfaction with an inhaler can vary with different inhalers.^{29,30} Despite this, we did not explore differences in satisfaction by inhalers because it is not an objective of our study. However, we are planning a future study on these issues. Moreover, we did not find statistically significant differences in adherence to inhalers between DPIs and pMDIs. This finding merits further research. It would also be interesting to assess potential differences in adherence with distinct DPIs or pMDIs. Nevertheless, due to the different characteristics of inhalers,¹⁰ it is important to choose the most appropriate inhaler for each patient.

A potential limitation of our study was that adherence was reported by the patients, but we were not able to confirm whether they took their medication every day. This might alter our findings. However, we could have chosen other methods to assess adherence. Direct methods, such as measurement of drug plasma levels or the use of electronic devices, are more sensitive but also more complicated and expensive. Among indirect methods, validated self-reported questionnaires or scales are easy to administer.³¹ We chose the Morisky-Green questionnaire because it is widely used in clinical practice and research. Moreover, we assessed specific adherence to an inhaler by using the TAI, which is a reliable and validated instrument for establishing adherence.¹⁸ By using these two instruments, we considered that we could obtain a reasonable estimation of adherence.

Some findings of our study need more investigation. Satisfaction was higher in men and younger patients, and those with earlier asthma diagnosis or onset of therapy. Other studies found that satisfaction was higher in older patients.³² Furthermore, in our study, although satisfaction was higher in younger patients or those with moderate asthma, adherence to treatment was higher in older patients and those with severe asthma. We suggest that these variables were not completely related and, in addition, older patients showed greater adherence than younger patients.²⁷ All these findings deserve further research.

CONCLUSION

The patients' satisfaction with their inhaler is associated with higher adherence and asthma control. Our results point out the relevance of inhaler choice in inhaled therapy and could be useful for designing new strategies targeted to increase adherence in patients with asthma.

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