

Patient satisfaction with beclomethasone dipropionate nasal aerosol device with integrated dose counter during daily use

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ABSTRACT

Some patients with allergic rhinitis (AR) may prefer a “dry” intranasal corticosteroid aerosol to avoid certain sensory perceptions such as the “wet feeling in the nose” and the “dripping down the throat” associated with aqueous nasal sprays. A nonaqueous hydrofluoroalkane-propelled beclomethasone dipropionate (BDP) nasal aerosol with an established efficacy and safety profile was approved to treat the nasal symptoms associated with AR in adult and adolescent patients. This study was designed to evaluate ease of use and patient satisfaction with the BDP nasal aerosol device in patients with perennial AR (PAR). In this phase 3, randomized, double-blind, parallel-group, placebo-controlled study, eligible patients (≥ 12 years of age) with PAR were randomly assigned to receive BDP nasal aerosol at 320 micrograms/day or placebo for 6 weeks. At the end of the treatment period, patients assessed device ease of use and satisfaction with the device using a questionnaire with a 5-point representative scale (not at all, not very, neither nor, somewhat, very [certain/easy/satisfactory]). Nearly all patients (89.7%) reported that the BDP nasal aerosol device with integrated dose counter was “very easy” or “somewhat easy” to use. The majority of patients (87.5%) also indicated that it was “very easy” or “somewhat easy” to tell when the device was empty, compared with only 42.3% who were “very certain” or “somewhat certain” of being able to tell when previously used aqueous nasal spray devices were empty. Overall, patient satisfaction with the BDP nasal aerosol device was high: 65.7% responded that they were “very satisfied” or “somewhat satisfied” and only 3.6% were “not satisfied at all” or “not very satisfied.” These results indicate that the majority of patients considered the BDP nasal aerosol device easy to use and reported a high degree of satisfaction with the device compared with other nasal sprays they had used in the past.

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Allergic rhinitis (AR) is an inflammatory disease of the nasal mucosa characterized by nasal congestion, rhinorrhea, pruritus, sneezing, and frequent association with eye symptoms including conjunctivitis.¹ Approaches to treat AR symptoms include allergen avoidance, immunotherapy, and pharmacologic therapy, particularly with intranasal corticosteroids (INSs), which are currently among the most effective medication class for the control of AR symptoms and therefore recommended as first-line therapy.^{2–5} However, until

recently, INS sprays were available only in aqueous formulations. The outcomes of two national surveys among adult patients with AR—the Nasal Allergy Survey Assessing Limitations and Allergies in America—indicate that bothersome side effects associated with these sprays were among the most common reasons for patient dissatisfaction and a frequent reason for discontinuation of medication.^{6,7} Discomfort from the spray and the sensation of medication dripping back down the throat significantly reduced patient satisfaction with INS sprays, and approximately one-third of AR patients considered these and other side effects moderately or extremely bothersome.^{6,7} Thus, there was an unmet need for a nonaqueous INS formulation that could help improve patients’ satisfaction with their therapy. Moreover, the availability of a nonaqueous (aerosol) formulation would increase the treatment choices for patients, which could ultimately lead to improved clinical benefits as a result of increased adherence to therapy because of increased satisfaction with daily treatment.³

Many different INS delivery devices are currently available with comparable safety profiles, although no clinical evidence supports superiority of any INS.³ Difficulty in using or lack of satisfaction with any of these nasal delivery devices may deter a patient from using the INS device as prescribed. Accordingly, patient adherence

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with daily dosing and long-term adherence to prescribed medication schedules may be enhanced by patient satisfaction with ease of use of the delivery device. Additionally, most devices for delivery of INSs do not include an integrated dose counter, which may lead to premature discarding or usage of the device beyond the labeled number of doses. It is likely that an easy-to-use and helpful device would also help increase patients' satisfaction with their daily therapy and could lead to improved clinical benefits because of continued adherence to therapy.

Beclomethasone dipropionate (BDP), an anti-inflammatory corticosteroid shown to be efficacious and safe for the treatment of AR,⁸ has been previously formulated as an aqueous nasal spray (Vancenase AQ; Schering Corp., Kenilworth, NJ and Beconase AQ; Glaxo-SmithKline, Research Triangle Park, NC). BDP was also previously available as a chlorofluorocarbon (CFC)-propelled formulation (Beconase and Vancenase Pockethaler). However, as mandated by the Montreal Protocol, CFC-containing nasal aerosols have been discontinued because of environmental concerns, such that these formulations are no longer available.⁹ A CFC-free formulation of BDP, as a nonaqueous aerosol solution propelled by hydrofluoroalkane and delivered from a novel device with an integrated dose counter, has been approved as of March 2012, by the United States Food and Drug Administration for the treatment of nasal symptoms associated with seasonal and perennial AR (PAR) in adults and adolescents aged ≥ 12 years.¹⁰ In this study, we evaluated ease of use and patient satisfaction with the BDP nasal aerosol device with an integrated numerical dose-counting mechanism in patients with PAR.

METHODS

Study Design

Ease of use and patient satisfaction with the BDP nasal aerosol device were evaluated as part of a 6-week, phase 3, randomized, double-blind, parallel-group, placebo-controlled, multicenter, efficacy and safety study in adolescent and adult patients with PAR conducted in 2010, a period when no marketed INS device included an integrated dose counter (ClinicalTrials.gov identifier: NCT01134705). Detailed study design, the primary end point of efficacy over the 6-week treatment period, other efficacy, and safety outcomes have been previously reported.¹¹ The study was approved by Quorum Review (Seattle, WA) and conducted in compliance with Good Clinical Practice guidelines and in accordance with the principles of the revised version of the Declaration of Helsinki. All patients provided written informed consent or assent before any study activity, as age appropriate.

The study consisted of two periods, a placebo run-in period (7–21 days from the screening visit to the randomization visit) followed by the treatment period (43

days from the randomization visit to the final treatment visit). Patients were randomly assigned in a 1:1 ratio to receive either BDP nasal aerosol (320 $\mu\text{g}/\text{day}$: 80 $\mu\text{g}/\text{actuation}$, 2 actuations/nostril) or placebo nasal aerosol (2 actuations/nostril) for 6 weeks. Patients self-administered the study medication once daily in the morning (A.M.) and assessed their nasal symptoms twice daily in the A.M. and evening (P.M.). At the final treatment visit, patients completed a Nasal Device Ease of Use and Satisfaction Questionnaire evaluating "ease of use of the device" and "patient's satisfaction with the device." This questionnaire consisted of 12 questions to assess patients' experience with other nasal sprays used in the past, experience with the study nasal aerosol device (ease of use), and satisfaction with the study nasal aerosol device compared with other nasal sprays used in the past. Responses to all questions were based on a 5-point scale ranging from "not certain/easy/satisfied at all" to "very certain/easy/satisfied" (Table 1).

Patients

Patients ≥ 12 years of age, of either sex, and any race, with a history of PAR for ≥ 2 years, general good health, and free of any concomitant conditions or treatment that could interfere with study conduct were included in the study. Additional eligibility and exclusion criteria have been previously described.¹¹

Study End Points and Statistical Analysis

The primary efficacy end point was the average A.M. and P.M. patient-reported reflective total nasal symptom score over the 6-week treatment period, which has been reported previously.¹¹ Ease of use and patients' satisfaction with the nasal device were evaluated as an additional end point. Summary statistics for patients' responses to the Nasal Device Ease of Use and Satisfaction Questionnaire were analyzed using the intent-to-treat (ITT) population. The ITT population included all randomly assigned patients who received at least 1 dose of randomized study medication and had at least 1 postbaseline assessment. In this study, data for placebo and BDP nasal aerosol treatment arms of the ITT population were combined as a single group because the study design was double-blinded and no difference in the devices used for placebo or BDP nasal aerosol existed other than the ingredient (active drug or placebo) in the canisters, and the outcomes of the Nasal Device Ease of Use and Satisfaction Questionnaire were similar for both treatment arms. The only exception to this was the overall satisfaction question, results of which were presented separately for the BDP nasal aerosol treatment arm because there was a possibility that the response to this question may have been influenced by the efficacy of the treatment. Patients who

Table 1 Sample questions from the Nasal Device Ease of Use and Satisfaction Questionnaire

Previous Nasal Spray Use*				
Considering other nasal sprays that you have used in the past...				
☐	☐	☐	☐	☐
Not certain at all	Not very certain	Neither certain nor uncertain	Somewhat certain	Very certain
How certain were you that you were able to tell that your nasal spray was empty?				
How certain were you that you were able to tell how much medication remains in those sprays?				
How certain were you that you were able to tell when it was time to refill your nasal spray device?				
Study Nasal Aerosol Device with Dose Counter				
Considering this nasal device with dose counter...				
☐	☐	☐	☐	☐
Not easy at all	Not very easy	Neither easy nor uneasy	Somewhat easy	Very easy
How easy was the nasal device with dose counter to use?				
How easy was it to tell how many doses remain in the nasal device?				
How easy will it be for you to tell when your nasal device is empty?				
How easy will it be for you to tell when the device needs to be replaced?				
Satisfaction with the Study Nasal Aerosol Device Compared with Other Nasal Sprays Used In The Past*				
Compared with other nasal sprays that you have used in the past...				
☐	☐	☐	☐	☐
Not satisfied at all	Not very satisfied	Neither satisfied nor unsatisfied	Somewhat satisfied	Very satisfied
How satisfied were you with this nasal device with dose counter?				
How satisfied were you with this nasal device with dose counter based on ease of use?				

*For patients who answered “yes” to using a nasal spray in the past. Nonresponders to this question included those who had not used a nasal spray in the past or had used a nasal spray in the past but did not answer the question.

did not answer a question were categorized as nonresponders (no response group) for that particular question. Nonresponders to questions related to previous use of aqueous nasal sprays included those who had not used a nasal spray in the past or had used a nasal spray in the past but did not answer the question.

RESULTS

Study Patients

The combined ITT population included 466 patients (Table 2), of whom 232 patients were randomly assigned to BDP nasal aerosol and 234 patients to placebo. The majority of patients (79.6%) were white, and 68.5% were female. The mean age was 37 years (range, 12–82 years). Mean adherence rates (with daily administration of study medication) were at least 96% in each treatment group.

Nasal Device Ease of Use and Nasal Device Satisfaction Outcomes

Patient’s Experience with Dose Tracking. When questioned about aqueous nasal spray devices used in the past, only 42.3% of patients were “very certain” or “somewhat certain” of being able to tell when the aqueous nasal spray devices were empty (Fig. 1). Less than half of the patients were “very certain” or “somewhat certain” of being able to tell how much medica-

Table 2 Patient demographics and baseline characteristics (ITT population)

	Total n = 466
Age, yr	
Mean (SD)	37.0 (14.1)
Median	37.5
Minimum-maximum	12–82
Sex, n (%)	
Female	319 (68.5)
Male	147 (31.5)
Race, n (%)*	
White	371 (79.6)
Black or African American	80 (17.2)
Asian	11 (2.4)
American Indian or Alaskan Native	3 (0.6)
Other	7 (1.5)
Ethnicity, n (%)	
Hispanic or Latino	56 (12.0)
Neither Hispanic nor Latino	410 (88.0)

*Patients were able to select more than one race type.

tion remained in the aqueous nasal sprays they had used in the past (34.3%) or when it was time to refill an aqueous nasal spray device they had used in the past (40.6%; Fig. 1). In contrast, nearly all (87.6%) study

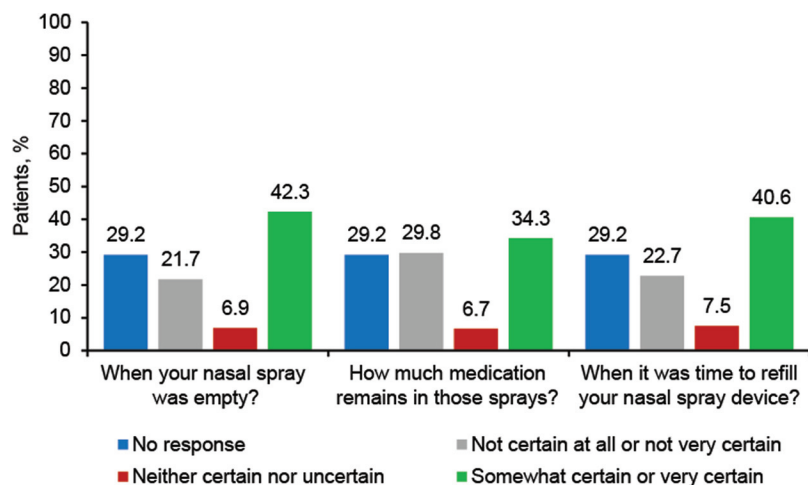


Figure 1. Patient responses to questions on experience (ease of use) with the aqueous nasal sprays that they had used in the past ($n = 466$). Nonresponders (no response group) to this question included those who had not used a nasal spray in the past or had used a nasal spray in the past but did not answer the question.

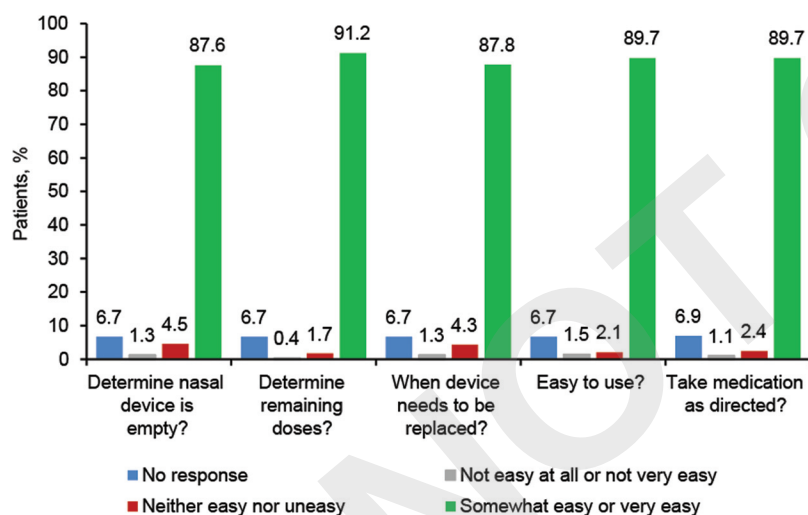


Figure 2. Patient responses to questions on experience (ease of use) with the study nasal aerosol device ($n = 466$). Nonresponders (no response group) to this question were limited to those who did not answer the question.

patients reported that, when using the study nasal aerosol device, it was “very easy” or “somewhat easy” to tell when the nasal aerosol device was empty (Fig. 2). Furthermore, most patients reported that it was “very easy” or “somewhat easy” to tell how much medication remained in their study nasal aerosol device (91.2%) or when it was time to replace the nasal aerosol device (87.8%; Fig. 2).

Ease of Use with Study Nasal Aerosol Device. Nearly all patients (89.7%) reported that the study nasal aerosol device with the integrated dose counter was “very easy” or “somewhat easy” to use (Fig. 2). None of the patients who participated in the treatment period discontinued because of issues with the device. Most study patients (89.7%) also indicated that with the study device, it was “very easy” or “somewhat easy” to take their medication as directed (Fig. 2).

Satisfaction with the Nasal Aerosol Device Compared with Other Nasal Sprays Used in the Past. Among all patients, overall satisfaction with the nasal aerosol device with dose counter was high. The majority (65.7%),

when analyzed in both responders and nonresponders to the question, reported that they were “very satisfied” or “somewhat satisfied” with the nasal aerosol device; only 3.6% of patients indicated that they were “not satisfied at all” or “not very satisfied” (Fig. 3). Most patients (65.5%) reported to be either “very satisfied” or “somewhat satisfied” with ease of use of the nasal aerosol device, and a similar proportion (65.5%) reported such satisfaction with respect to being able to determine when the device needed to be replaced (Fig. 3).

Satisfaction with the BDP Nasal Aerosol Device Compared with Other Nasal Sprays Used in the Past. To avoid introduction of potential bias resulting from efficacy of treatment, results of the question about nasal spray devices used previously are presented separately for the patients in the ITT group who had received BDP nasal aerosol treatment after randomization ($n = 232$). The majority (66.4%) responded that they were “very satisfied” or “somewhat satisfied” with the BDP nasal aerosol device compared with other nasal sprays used in the past; only 3.4% of patients were “not satisfied at

Figure 3. Patient responses on satisfaction with the ease of use with the study nasal aerosol device compared with other nasal sprays used in the past ($n = 466$). Nonresponders (no response group) to this question included those who had not used a nasal spray in the past or had used a nasal spray in the past but did not answer the question.

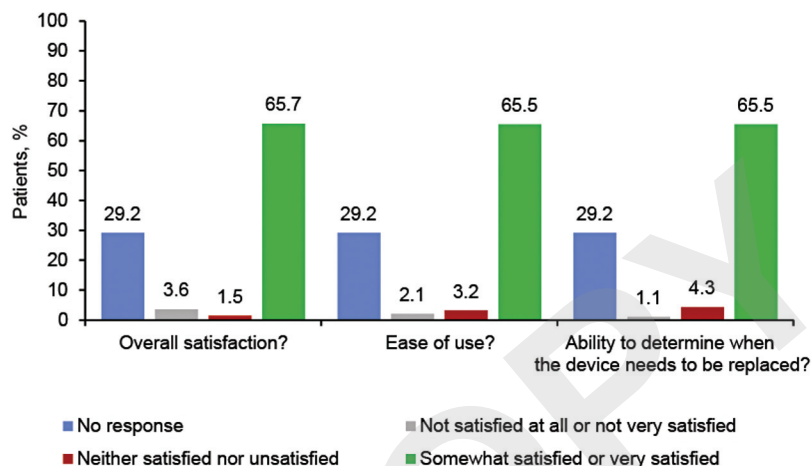
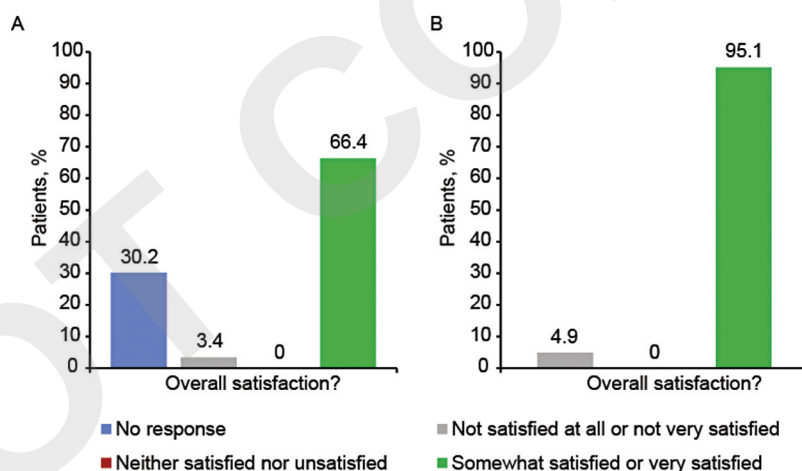


Figure 4. Patient response on overall satisfaction with the beclomethasone dipropionate (BDP) nasal aerosol device compared with other nasal sprays used in the past: (A) Nonresponders included ($n = 232$); (B) responders only ($n = 162$). Nonresponders (no response group) to this question included those who had not used a nasal spray in the past or had used a nasal spray in the past but did not answer the question. Data presented here are only for the BDP nasal aerosol treatment arm ($n = 232$), excluding the placebo device users.



all” or “not very satisfied” (Fig. 4). However, when patients in the BDP nasal aerosol treatment group who did not respond to this question were excluded from the analysis (no response group; $n = 162$), a high percentage, 95.1%, reported that they were “very satisfied” or “somewhat satisfied” with the BDP nasal aerosol device compared with other nasal sprays used in the past; only 4.9% of patients indicated that they were “not satisfied at all” or “not very satisfied” (Fig. 4). Among placebo patients, 65.0% were “very satisfied” or “somewhat satisfied” with the nasal aerosol device compared with previously used nasal spray devices (data not shown).

DISCUSSION

In patients with asthma or chronic obstructive pulmonary disease, patient preference for and treatment satisfaction with an inhaler may promote adherence to treatment and thereby improve the efficacy of therapy.¹² Similarly, satisfaction and comfort with an intranasal treatment device are likely to enhance adherence to that treatment among patients with AR.¹³ In this study, device ease of use and patient satisfaction with the BDP nasal aerosol device in patients with PAR

were evaluated. These results indicate that most patients considered the BDP nasal aerosol device easy to use and that, overall, they reported a high degree of satisfaction with the device compared with other nasal sprays they had used in the past. Less than 50% of patients reported a positive experience (ease of use) with the aqueous nasal sprays that they were previously using. In contrast, ~90% of patients reported a positive experience with the current study device, including ease of use, ability to determine the number of remaining doses, and ability to determine when the device was empty or required replacement.

Most patients found it “very easy” or “somewhat easy” to take their medication as directed using the study nasal aerosol device. This perception may have been derived from at least two features of the device: nonaqueous aerosol delivery and the integrated dose/actuation counter. Nonaqueous aerosol delivery of an INS is likely to be preferred by many patients because the “dry” application does not cause anterior and posterior runoff of liquid, thus generating less of the “wet” or “drippy” feeling reported with aqueous nasal sprays that may render patients less likely to adhere to treatment.^{3,14,15} Optimization of product formulation,

such as aerosol delivery, to meet patient sensory preferences has therefore been proposed as a means to increase patient adherence to INS therapy.³ Patient preferences for the sensory attributes of different INSS can drive adherence, influence disease control, and ultimately impact health care costs.¹⁶

Aerosol/spray delivery devices that are easy to use and facilitate dose tracking may lead to improved patient satisfaction and adherence. In a separate analysis of data from this study by Meltzer *et al.*,¹⁷ the BDP nasal aerosol device with an integrated dose counter was shown to be accurate and functional during daily use by adult and adolescent PAR patients. Integration of an actuation counter will enable patients to track remaining medication, monitor medication usage, and avoid running out of medication, all of which is likely to give patients more control and reassurance, and thus may increase their sense of satisfaction.^{18–22} However, because the dose counter is integrated into the delivery device, it is hard to differentiate satisfaction with the dose counter in particular versus the nasal device as a whole. Nasal spray or nasal aerosol devices with either integrated dose indicators lacking any numerical display or dose indicators indicating the remaining actuations in groups of 5 or 10 have been previously developed.^{23,24} This BDP nasal aerosol device is the first nasal metered-dose inhaler with an integrated dose counter that can count downward and numerically display every actuation from 120, when the medication canister is full, to 0, when the canister is empty. Thus, this additional feature may have also contributed to overall patient satisfaction with the device.

The results presented in this study include the subset of patients who did not respond to the respective question (no response group). No response to a question could be because of personal choice not to respond to a question or to having no experience with another nasal spray in the past. The Nasal Device Ease of Use and Satisfaction Questionnaire provided patients with an option not to answer any questions about previous nasal spray usage and overall satisfaction if the patient did not previously use a nasal spray. This ensured accurate responses based on actual usage experience rather than forcing a response from each participant. When the no response group was removed from the analysis, the overall response rate increased to 95.1%, indicating a more realistic patient assessment of overall satisfaction with the BDP nasal aerosol device. Removal of the nonresponders provided greater clarity to the overall response rate presented for all other outcomes in this analysis (data not shown).

In this study, placebo ($n = 234$) and BDP nasal aerosol groups ($n = 232$) were combined because the study design was double-blinded (*i.e.*, the active and placebo devices were identical). Also, the outcomes of the questionnaire were similar for the BDP and placebo treat-

ment groups. However, it may be difficult to differentiate overall patient satisfaction with the study device versus overall satisfaction with the study treatment because there was a possibility that the response may have been influenced by the efficacy (for the BDP group) or perceived efficacy (for the placebo group) of the treatment. In this analysis, the results suggest that patient response was not influenced by the efficacy component of treatment because overall patient satisfaction was comparable between the BDP nasal aerosol treatment group (66.4%) and placebo group (65.0%).

A potential limitation of this study is the effect of recall bias, in that patients may not accurately remember their experiences, *e.g.*, they may not recall minor difficulties with devices used previously. Although such recall error has the potential to skew patient responses, devices with an integrated dose counter were not commercially available in the United States during the time of the study, although devices with simple dose indicators were available (*e.g.*, fluticasone furoate nasal spray). Similarly, during the time of the study, there were no commercially available nasal aerosols for patient use. Therefore, this device may have provided a unique experience for study participants.

The high degree of satisfaction observed in this study with the BDP nasal aerosol device suggests that this new aerosol device with an integrated dose counter may address some of the key undesirable attributes associated with currently available aqueous INS devices. Patient adherence to effective treatment is central to the management of AR and can control symptoms effectively and improve quality of life, thus allowing patients to maintain normal and productive lives. However, as many as one-third of AR patients report dissatisfaction with their prescription, and more than two-thirds of patients take their medication inconsistently.²⁵ The authors speculate that the high degree of patient satisfaction observed in this study suggests that the BDP nasal aerosol may improve patient adherence to their prescribed treatment regimen. However, the current study was not designed to substantiate this conclusion. To further confirm this potential link between satisfaction and adherence, future studies are needed, including those specifically designed to evaluate the effect of patient satisfaction with the BDP nasal aerosol device on adherence to treatment.

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