

Beclomethasone Dipropionate Nasal Aerosol in Patients with Perennial Allergic Rhinitis (BALANCE) study: 6-month results

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ABSTRACT

Background: Perennial allergic rhinitis (PAR) exerts significant quality-of-life and economic burdens on society. Beclomethasone dipropionate (BDP) nasal aerosol is the first nonaqueous, hydrofluoroalkane-propelled intranasal corticosteroid approved for patients in the United States to treat PAR and seasonal allergic rhinitis.

Objective: To evaluate real-world effectiveness of BDP nasal aerosol from the patient's perspective by using a postmarketing observational registry.

Methods: Patients (N = 824) from 43 U.S. study sites completed monthly patient-reported outcome instruments, including the Rhinitis Control Assessment Test (primary outcome variable), Treatment Satisfaction Questionnaire for Medication, Work Productivity and Activity Impairment Questionnaire plus Classroom Impairment Questions: Allergy-Specific, Pittsburgh Sleep Quality Index, and Mini Rhinoconjunctivitis Quality of Life Questionnaire for 6 months.

Results: The primary outcome assessment (Rhinitis Control Assessment Test score) (N = 527) indicated significant symptomatic improvement over baseline beginning at month 1 ($p < 0.001$), with >78.8% of respondents who achieved clinically meaningful improvement over 6 months. Secondary outcome measures Mini Rhinoconjunctivitis Quality of Life Questionnaire ($p < 0.001$), Pittsburgh Sleep Quality Index ($p < 0.001$), and Treatment Satisfaction Questionnaire for Medication–9 scales of effectiveness ($p < 0.001$), global satisfaction ($p = 0.001$), and patient-rated convenience ($p = 0.03$), significantly increased from baseline to month 6. Five of seven measurements of the Work Productivity and Activity Impairment Questionnaire plus Classroom Impairment Questions: Allergy-Specific, with the exception of work time missed and class time missed, were significantly ($p < 0.001$) improved in patients treated with BDP compared with baseline.

Conclusions: Treatment with nonaqueous BDP nasal aerosol in a real-world setting significantly improved PAR symptoms and measures of quality of life, work, and school-related activities, and is associated with high patient satisfaction, reduced productivity loss and activity impairment, and improvement in sleep quality.

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Perennial allergic rhinitis (PAR) is a symptomatic disorder of the nasal mucous membranes caused by immunoglobulin E mediated inflammation after exposure to indoor or outdoor environmental allergens.¹ Characteristic symptoms include nasal discharge (rhi-

norrhea), nasal blockage (congestion), sneezing, and/or itching of the eyes, nose, and throat.² Although PAR is generally not associated with severe morbidity or mortality, it exerts significant quality-of-life and economic burdens on society.^{3,4}

Guidelines from the American Academy of Allergy, Asthma & Immunology, and also those from the American College of Allergy, Asthma & Immunology recommend intranasal corticosteroid (INS) treatment as the most effective medication class for controlling symptoms of allergic rhinitis (AR).⁵ Therapy with INS is aimed at treating the allergen-induced inflammatory response and has been shown to be more effective than antihistamines and leukotriene inhibitors for reducing nasal symptoms associated with PAR.⁵ Products in this class have comparable safety and efficacy but are differentiated by chemical composition, formulation, and delivery system. These factors can affect sensory perceptions (smell, taste, aftertaste, feel of spray in the nose and/or throat, amount of spray running out of the

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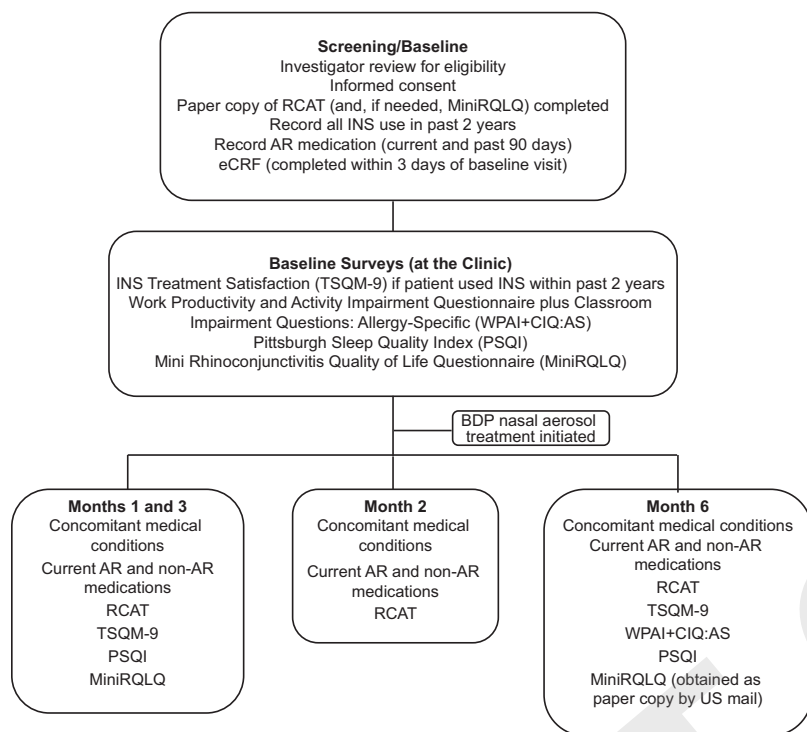


Figure 1. Overall study schema. AR = Allergic rhinitis; BDP = beclomethasone dipropionate; INS = intranasal corticosteroid; RCAT = Rhinitis Control Assessment Test.

nose or down the throat), and influence patient preferences and adherence to dosing regimens.^{6,7}

Beclomethasone dipropionate (BDP) nasal aerosol is a nonaqueous, aerosolized INS spray delivered by a hydrofluoroalkane propellant. The drug was approved by the U.S. Food and Drug Administration for the treatment of symptoms of PAR and seasonal AR (SAR) in adult and adolescent patients in 2012, and, as of 2014, in patients ≥ 4 years of age.⁸ BDP nasal aerosol is the first hydrofluoroalkane-propelled INS formulation available to patients in the United States. Long-term efficacy and safety of BDP nasal aerosol was demonstrated in a 30-week, double-blind, placebo-controlled study conducted in 529 patients with PAR.⁹

Analysis of available data indicated that moderate-to-severe allergy symptoms are associated with a high degree of impairment at work and in the classroom, and while engaging in other regular activities.¹⁰ Some estimates indicate that the most significant economic cost of AR arises from at-work productivity losses due to symptoms and adverse effects of antiallergic medications.¹¹ A comprehensive national survey that included 2500 adults diagnosed with AR reported that nasal allergies interfered with work (35% of patients to a moderate level), led to missed workdays (30% of patients), and had a negative effect on patient quality of life (25% of patients to a moderate level).¹²

Therefore, the effectiveness of BDP nasal aerosol for PAR was evaluated from the patient's perspective in this observational study, which focused on (1) rhinitis control, (2) INS therapy satisfaction, (3) work and usual

activity impairment, (4) nighttime sleep problems, and (5) health-related quality of life (HRQOL) in a real-world setting. The design of the present survey-oriented study was twofold: to help define the substantial effects of PAR on patient wellness and to initiate a critical tool to evaluate, from the patient's perspective, treatment outcomes with BDP nasal aerosol in the management of PAR under real-world conditions. The present article summarized changes in assessment scores from baseline to the end of 6 months of follow-up.

METHODS

Study Design and Patients

The Beclomethasone Dipropionate Nasal Aerosol in Patients with Perennial Allergic Rhinitis (BALANCE) study was a postmarketing, prospective, observational, single-arm, open-label registry study with a 6-month follow-up initiated to investigate the effectiveness of BDP nasal aerosol from the patient's perspective under real-world conditions. The registry recruited patients from 43 study sites (allergy/immunology, otolaryngology, and primary care clinics) in the United States and screened them for eligibility. The registry enrolled patients who had a diagnosis of PAR for ≥ 1 year and who began using BDP nasal aerosol 320 μg administered as 2 sprays in each nostril once daily after enrollment in this study. The overall study schema is presented in Fig. 1.

Male or female patients ages of ≥ 12 years with a diagnosis of PAR for ≥ 1 year, a positive epicutaneous or serum-specific immunoglobulin E test to a perennial allergen as appropriate for the location within the past 2 years, and PAR symptoms consistent with exposure to the tested allergen for ≥ 1 year were included in the study. Uncontrolled rhinitis symptoms were required to be present at the time of assessment as confirmed by a score of ≤ 21 on the Rhinitis Control Assessment Test (RCAT). Within 7 days before enrollment, the patients were prescribed BDP nasal aerosol 320 $\mu\text{g}/\text{day}$ as 2 sprays in each nostril once daily, but use was not initiated until after study enrollment. Patients were excluded if they had current acute or chronic sinusitis or chronic purulent nasal discharge, rhinitis medicamentosa, or nasal structural abnormalities (including nasal polyps and clinically significant nasal septum deviation) that significantly interfered with nasal airflow, acute upper respiratory infection within the past 14 days, use of any pressurized metered-dose inhaler INS product (including BDP nasal aerosol or ciclesonide nasal aerosol) within the past 90 days, or any experimental therapy for AR within the past 30 days. Written informed consent was obtained for all the patients before they entered the study.

The protocol was submitted to and required unconditional approval in writing by the appropriate ethics committee or institutional review Board). This study was conducted in full accordance with the International Council on Harmonisation Good Clinical Practice Consolidated Guideline (E6) and any applicable national and local laws and regulations relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. The principles of Informed Consent, Declaration of Helsinki and its updates, and current Good Clinical Practice; the provisions of International Council on Harmonisation, United States Code of Federal Regulations, and local country regulations; and the sponsor's standard operating procedures were followed.

Assessments

Unless otherwise specified, data were collected monthly (within a 7-day window) *via* completed electronic patient-reported outcome (PRO) instruments housed on the study Web site. At study enrollment, the patients were given instructions to log onto the study Web site, and they also received electronic reminders to complete their surveys. Online data monitoring was used for compliance, and data were captured within a validated clinical data management system. Baseline values allowed for the assessment of the effect of PAR on patient wellness as measured by the assessments described below.

Primary Outcome Assessment

The primary outcome assessment was the RCAT, a PRO tool developed in accordance with U.S. Food and Drug Administration guidelines¹³ and validated in patients ≥ 12 years of age with SAR and PAR.¹⁴ The RCAT is a 6-item questionnaire that assesses control of nasal and other allergy symptoms, with response categories that range from 1 (worst) to 5 (best) summed to produce a total score; total scores in the 5 to 14 range indicate no control of rhinitis symptoms, total scores in the 15 to 21 range indicate rhinitis symptoms that are somewhat controlled, and total scores in the 22 to 30 range indicate well-controlled rhinitis symptoms. The recommended minimal important difference in RCAT score for determining a change in rhinitis control is 3 points. The RCAT was completed on paper at the first and only office visit and then *via* the study Web site for each subsequent monthly assessment through month 6.

Secondary Outcome Assessments

The Treatment Satisfaction Questionnaire for Medication (TSQM-9) is an abbreviated, 9-item version of the TSQM and a reliable and valid measure to assess treatment satisfaction in a real-world study design.¹⁵ Three subscales of the TSQM-9 (effectiveness, convenience, and global satisfaction) are scored separately (there is no overall score) and were used in the present study to determine the level of patient satisfaction with current or recent use of INS. Response categories range from 1 to 5 or 1 to 7, with higher scores representing greater treatment satisfaction. Patients with no INS experience within 2 years before the study did not complete this scale until the 1-month assessment.

The Work Productivity and Activity Impairment Questionnaire plus Classroom Impairment Questions: Allergy-Specific is a validated, 9-item PRO instrument that assesses the impact of allergies on work or school attendance and performance, and on other daily activities.¹⁰ Questions queried whether the respondent was employed or a student, number of hours worked or in school, hours missed due to allergy, degree that allergy affected productivity, and degree that allergy affected regular activities over the time span of the preceding 7 days. From these answers, four scores could be derived: absenteeism (lost work time), presenteeism (impairment at work), work productivity (overall lost work productivity), and activity impairment, with higher numbers indicating greater impairment and less productivity. This questionnaire was completed at baseline and months 1 and 6.

The Pittsburgh Sleep Quality Index (PSQI) is a 19-item, self-rated questionnaire that assesses sleep quality and disturbances over a 1-month interval and was completed at baseline and months 1, 3, and 6.¹⁶ Items

in the PSQI are grouped into seven components or domains (subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction over the past month), and each is scored on a 0 to 3 scale; a global sum of ≥ 5 indicates a “poor” sleeper.

HRQOL was assessed with the Mini Rhinoconjunctivitis Quality of Life Questionnaire (MiniRQLQ), which is an abbreviated, 14-item version of the full RQLQ and covers five domains: activity limitations, practical problems, nose symptoms, eye symptoms, and other symptoms.¹⁷ The patients responded to each question by using a 7-point scale (0, not troubled; 6, extremely troubled), which produced five domain scores and an overall score. The MiniRQLQ was completed on paper at both baseline (first clinic visit) and at the 6-month follow-up (returned to the study site *via* U.S. mail).

Statistical Analyses

Only patients who completed each of the assessments at every scheduled time point and indicated that he or she was a current BDP user at month 6 were included in the analysis. If patients met these criteria as well as completed each scheduled assessment for secondary end points, then they were included in the secondary end point analysis (TSQM-9, Work Productivity and Activity Impairment Questionnaire, PSQI, and MiniRQLQ). Patients who did not complete all of the secondary end point assessments at all of the prescribed time points were excluded from secondary analyses. Descriptive statistics included frequency distributions reporting mean, standard deviation, median, and interquartile range or proportions as appropriate. Repeated measures analysis was used to determine change in raw RCAT score over time and to demonstrate sustainability of change. Paired *t*-tests were used to determine change from baseline to month 6 for all outcome assessments. Statistical significance was set at $p < 0.05$ with 95% confidence intervals. Statistical analyses were conducted by using IBM SPSS Statistics for Windows version 22 (IBM Corp., Armonk, NY).

RESULTS

Patient Disposition and Demographics

Of 839 screened patients, 824 patients from 43 U.S. centers met entry criteria and were eligible for enrollment in the study. Of these patients, 710 (86.2%) completed the 6-month study and constituted the completer population used for the primary analyses of change from baseline to month 6. The total population in the current analysis was 527 patients, which represented individuals who indicated current use of BDP at month 6 and completed all scheduled instrument measurements throughout the

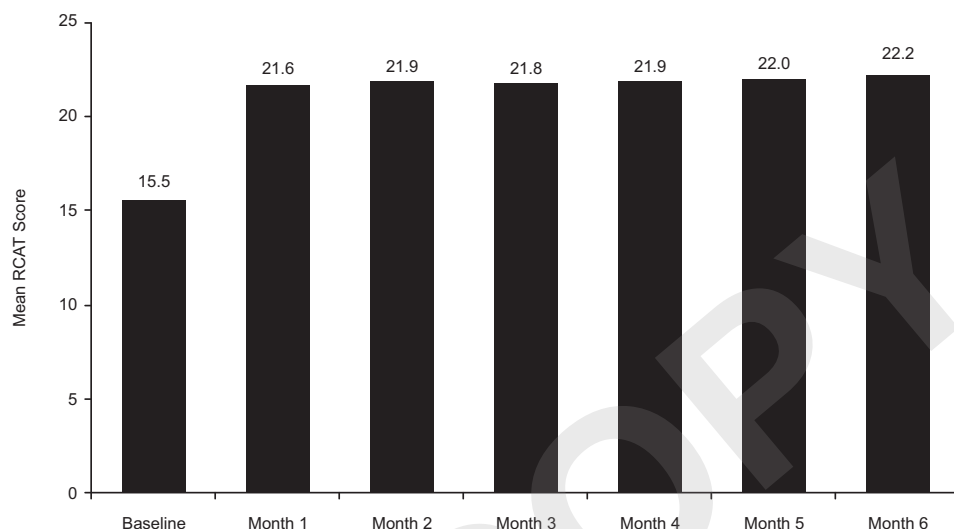
Table 1 Participant demographics

Parameter	
Sex, no. (%)	
Female	325 (61.7)
Male	202 (38.3)
Age, mean $\pm$ SD, y	38.8 $\pm$ 16.1
Race, no. (%)	
White	439 (83.3)
Black	56 (10.6)
Asian	28 (5.3)
Native Hawaiian or other Pacific Islander	2 (0.4)
Other	2 (0.4)
Ethnicity, no. (%)	
Hispanic	61 (11.6)
Employment, no. (%)	
Employed	286 (54.3)
Attends class	84 (15.9)
Employed and attends class	53 (10.1)
Not employed or attending class	99 (18.8)
History of SAR, no. (%)	402 (76.3)
PAR, no. (%)	
Dog	239 (45.4)
Cat	319 (60.5)
Dust mite	422 (80.1)
Cockroach	134 (25.4)
Feather	41 (7.8)
Mold	262 (49.7)
Other	78 (14.8)
Previous intranasal corticosteroid medications, no. (%)	263 (49.9)
Comorbidities, no. (%)	
Asthma	151 (28.7)
Hypertension	87 (16.5)
Gastroesophageal reflux disease	78 (14.8)
Headache	66 (12.5)
Depression	37 (7.0)
Hypercholesterolemia	42 (8.0)
Hypothyroidism	40 (7.6)
Drug hypersensitivity	35 (6.6)
Anxiety	28 (5.3)
Migraine	23 (4.4)

SD = standard deviation; SAR = seasonal allergic rhinitis; PAR = perennial allergic rhinitis.

study. Patient demographic characteristics are summarized in Table 1. The majority of participants in the analysis group were female and white, had a mean age of 38.8 years, and were working and/or attending school. The majority of patients also had a history of SAR, and the most common cause of PAR was dust mites, followed by cats. Nearly half of the study patients had previously used INS medications,

Figure 2. Mean Rhinitis Control Assessment Test scores at baseline through month 6 in patients who completed each of the assessments at every scheduled time point and indicated that he or she was a current beclomethasone dipropionate nasal aerosol user at month 6 ($n = 527$). A p value of <0.05 was based on changes from baseline over the 6-month treatment period when using a repeated measures analysis. RCAT = Rhinitis Control Assessment Test.



and many had comorbidities, the most common of which were asthma and hypertension.

Primary Outcome

The mean baseline RCAT score was 15.5 (indicative of poor symptom control) before treatment with BDP nasal aerosol (Fig. 2). A clinically meaningful (minimal important difference of ≥ 3 points) improvement in symptom control occurred as early as month 1 and was sustained throughout the remainder of the 6-month BDP nasal aerosol treatment period ($p < 0.05$). After 6 months of treatment with BDP nasal aerosol, $>78.8\%$ of patients had a clinically meaningful improvement in RCAT from baseline. Although no patient had symptom control (RCAT score of ≥ 22) at baseline, 58.8% of patients had achieved symptom control by month 6. Regardless of the level of symptom control at baseline, the majority of patients were able to achieve a higher level of symptom control at study end (Fig. 3, A and B).

Secondary Outcomes

Patient satisfaction with BDP nasal aerosol treatment, shown as significant improvements from baseline to month 6 in the mean scores of the TSQM-9 subscales (effectiveness, $p < 0.001$; convenience, $p = 0.03$; and global satisfaction, $p = .001$) is presented in Fig. 4. Patient-assessed improvements in effectiveness increased by >20 points from baseline to month 6. Treatment with BDP nasal aerosol improved the impact of allergies on work, school, and other activities, as measured by the significant increase in the mean scores for impairment at work ($p < 0.001$), overall work impairment ($p < 0.001$), impairment in class ($p = 0.001$), overall class impairment ($p = 0.001$), and activity impairment ($p < 0.001$) (Fig. 5) on the 9-item allergy-specific Work Productivity and Activity Impairment Questionnaire plus Classroom

Impairment Questions: Allergy-Specific. Although measures of work time missed and class time missed improved from baseline to month 6 with BDP treatment, these improvements were not statistically significant. Patients reported that treatment with BDP nasal aerosol improved sleep quality and decreased the impact of lack of sleep from baseline through month 6 as assessed by the PSQI survey; significant reductions were observed in all seven parameters (all $p < 0.001$) (Fig. 6). The global PSQI score was also significantly reduced from baseline through month 6 ($p < 0.05$) (Fig. 7). Disease-specific quality-of-life measures, including eye symptoms, were significantly improved from baseline through month 6 with BDP nasal aerosol treatment, as measured by the MiniRQLQ ($p < 0.001$ for all parameters) (Fig. 8).

Safety

During this study, a total of 415 patients (50.4%) reported 1446 adverse events. Twelve female patients reported 21 serious adverse events (atrial fibrillation, pericarditis, malignant and unspecified breast neoplasms [$n = 2$], general body pain, febrile neutropenia, acute pharyngitis, dysphagia, angina pectoris, shoulder pain, neck pain, blurred vision, spontaneous abortion [$n = 2$], hiatal hernia, gastroparesis, dyspnea, overmedication, cholecystitis, perforated bowel, and colon cancer). Five patients discontinued treatment due to adverse events, four due to serious adverse events (general body pain and febrile neutropenia in one patient who had breast malignancy, an angina pectoris episode [$n = 1$], spontaneous abortion [$n = 1$], and overdose of oxycodone [$n = 1$]). None of the adverse events were considered to be treatment related.

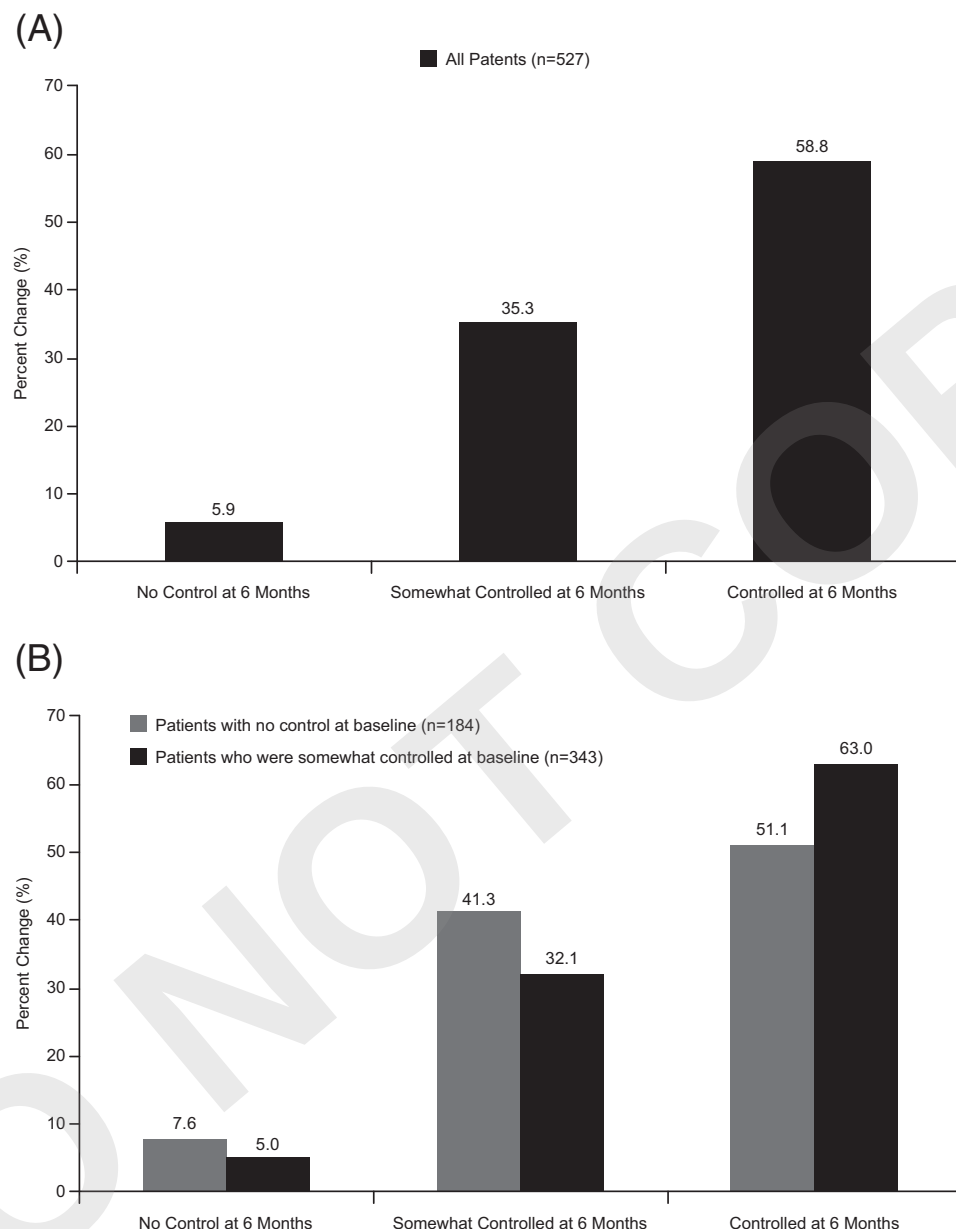


Figure 3. Rhinitis Control Assessment Test category change (6 months). (A) Includes patients who completed each of the assessments at every scheduled time point and indicated that he or she was a current beclomethasone dipropionate nasal aerosol user at month 6 ($n = 527$). (B) Stratifies results by patients who had no control at baseline (gray bars) ($n = 184$) and patients who were somewhat controlled at baseline (black bars) ($n = 343$). No patient was completely controlled at baseline, 34.9% of patients were not controlled at baseline, and 65.1% of patients were somewhat controlled at baseline.

DISCUSSION

The results of this study demonstrated that treatment with BDP nasal aerosol significantly improved PAR symptoms and measures of quality of life, work, and school-related activities. The key primary outcome measure, the RCAT score, demonstrated a clinically meaningful improvement in nearly 80% of patients who continued with their initial prescription of BDP nasal aerosol treatment for PAR over the 6-month period. Secondary outcome measures showed that BDP nasal aerosol led to a high level of satisfaction, re-

duced absenteeism, improved presenteeism, reduced work and classroom productivity loss, decreased activity impairment, improved sleep quality, and greater HRQOL.

Baseline levels of rhinitis symptoms in the BALANCE study, as measured by the RCAT score, indicated poor symptom control. Approximately 40% of those surveyed had impairments in work or class at baseline. Furthermore, the PSQI component scores for the overall population indicated that patients experienced some degree of sleep problems at baseline. These find-

Figure 4. Mean 9-Item Treatment Satisfaction Questionnaire for Medication (TSQM) scores at baseline and month 6 in patients who completed all Rhinitis Control Assessment Test assessments at every scheduled time point, indicated that he or she was a current beclomethasone dipropionate nasal aerosol user at month 6, and completed all TSQM assessments at every scheduled time point ($n = 42$).

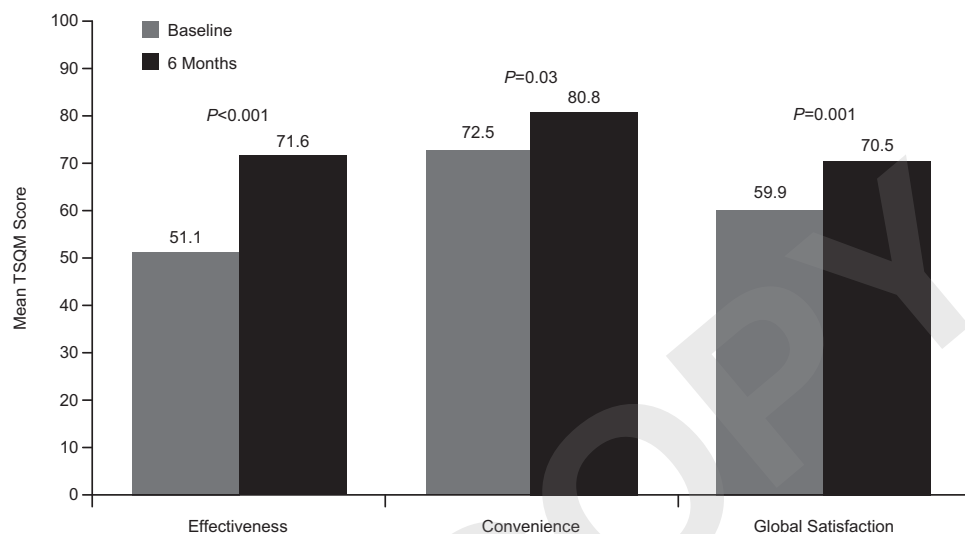


Figure 5. Mean percentage of patients who reported allergy-specific work productivity and activity impairment plus classroom impairment at baseline. Patients completed all Rhinitis Control Assessment Test assessments at every scheduled time point, indicated that he or she was a current beclomethasone dipropionate nasal aerosol user at month 6, and completed all allergy-specific work productivity and activity impairment plus classroom-impairment assessments at every scheduled time point.

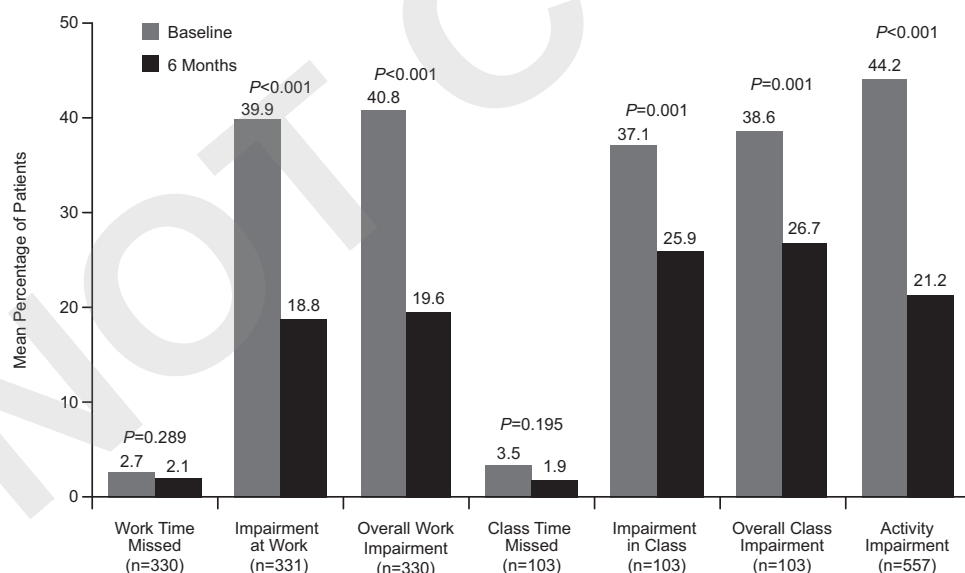
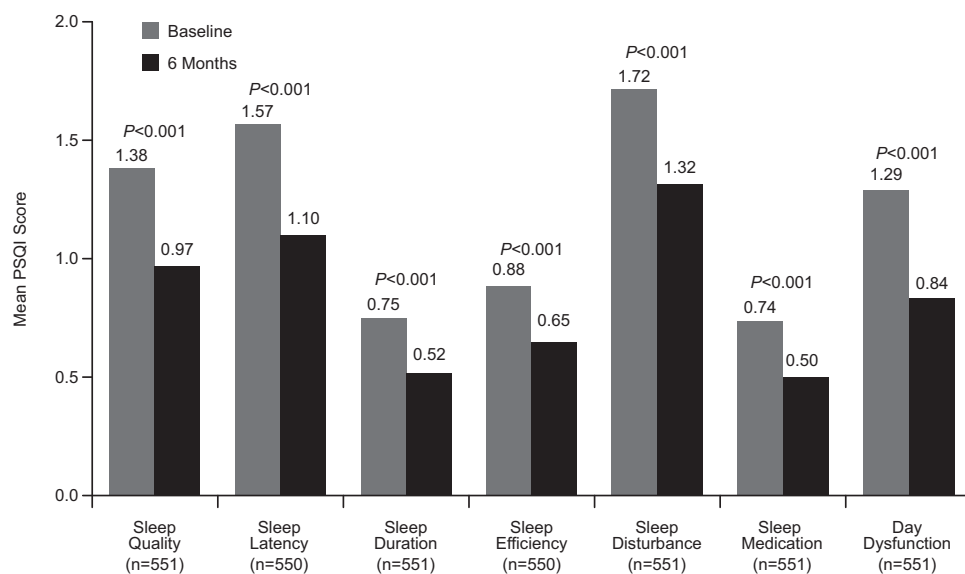


Figure 6. Mean Pittsburgh Sleep Quality Index (PSQI) scores at baseline and month 6 in patients who completed all Rhinitis Control Assessment Test assessments at every scheduled time point, indicated that he or she was a current beclomethasone dipropionate nasal aerosol user at month 6, and completed all PSQI assessments at every scheduled time point ($n = 551$).



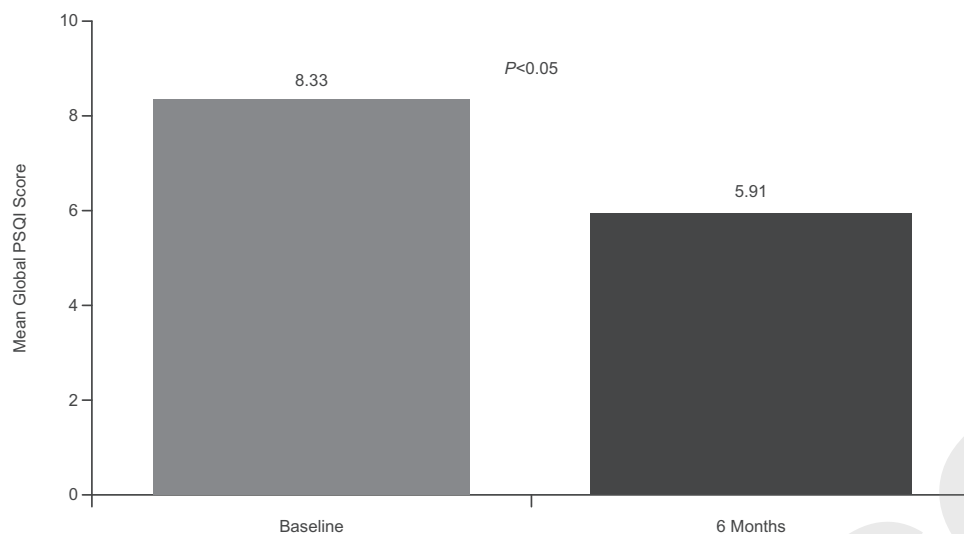


Figure 7. Mean global Pittsburgh Sleep Quality Index (PSQI) scores at baseline and month 6 in patients who completed all Rhinitis Control Assessment Test assessments at every scheduled time point, indicated that he or she was a current beclomethasone dipropionate nasal aerosol user at month 6, and completed all PSQI assessments at every scheduled time point ($n = 550$).

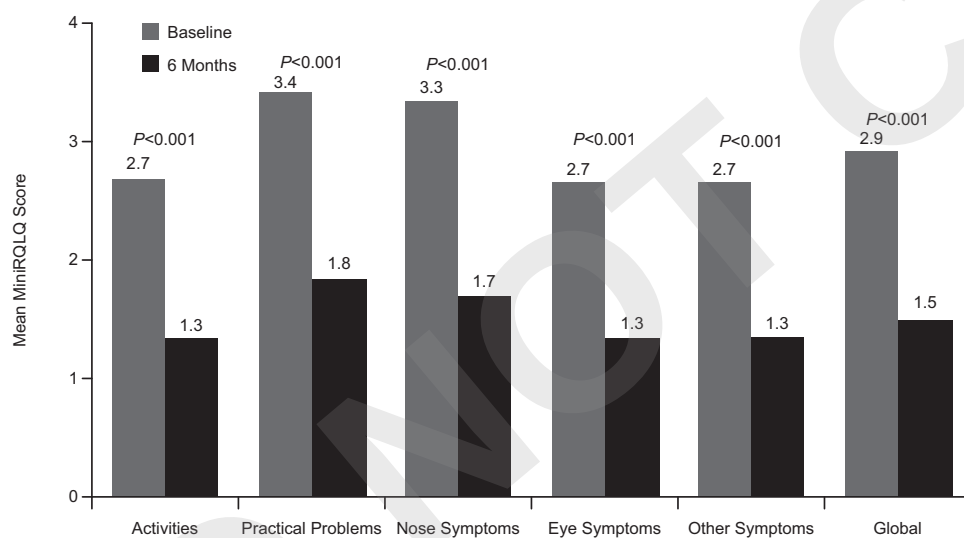


Figure 8. Mean Mini Rhinoconjunctivitis Quality of Life Questionnaire (MiniRQLQ) scores at baseline and month 6 in patients who completed all Rhinitis Control Assessment Test assessments at every scheduled time point, indicated that he or she was a current beclomethasone dipropionate nasal aerosol user at month 6, and completed all MiniRQLQ assessments at every scheduled time point ($n = 228$).

ings provided evidence of the varied effects of rhinitis on the patients beyond traditional rhinitis symptoms. No patient had rhinitis symptoms that were controlled at baseline as measured by their RCAT scores. All scores were <22 on the RCAT scale. Based on physicians' validation assessments for the RCAT, scores of >22 indicated that patients' rhinitis symptoms were completely or well controlled.¹⁸ In the present study, regardless of level of symptom control at baseline, all patients were able to achieve some level of symptom control after 6 months of treatment with BDP nasal aerosol (Fig. 3, A and B). In addition, treatment with BDP nasal aerosol for 6 months resulted in a clinically meaningful improvement in RCAT scores in $>78.8\%$ of patients. A clinically meaningful improvement is defined as a minimum important difference over time of at least 3 points in mean RCAT scores that would reflect a meaningful change in an individual patient's rhinitis control.¹⁴

The present study assessed a wide variety of outcomes, including symptoms, treatment satisfaction, work and school productivity, sleep quality, and HRQOL in an observation setting to determine the effect of BDP nasal aerosol on patients with PAR. Overall, all outcomes improved in response to treatment. In the present study, the MiniRQLQ was used to assess HRQOL and demonstrated improvement in each of the five component scores in response to treatment with BDP nasal aerosol. In addition, results from the PSQI, used to assess sleep quality and sleep disturbance, showed improvements in all seven component scores for the overall population after treatment with BDP nasal aerosol.

The BALANCE study was designed to collect data on an important population: patients with PAR who might have previously discontinued treatment with an aqueous INS formulation. Results of surveys indicated that 20% of patients with allergies are not fully satisfied

with their medications, and ~50% believe that they receive insufficient attention from their physicians.¹⁹ Noncompliance to prescribed therapeutic regimens is a global problem, particularly for allergy-based diseases in which symptoms vary from patient to patient and from season to season, and where a lack of efficacy is the number one reason for discontinuing medications.²⁰ Differences in chemical composition, formulation, and delivery systems of INS may influence sensations such as smell, taste, aftertaste, and feel of spray in the nose and throat,^{7,21} and possibly affect adherence to medication treatment regimens.⁶

Several studies were conducted to evaluate satisfaction and real-world outcomes for a variety of INS formulations.^{7,15,22,23} One such study evaluated the ease of use and patient satisfaction with BDP nasal aerosol as part of a 6-week, phase III, randomized, placebo-controlled trial.²³ Over the 6-week period, there was a trend that indicated greater ease of use and satisfaction with the study nasal aerosol device, and BDP specifically, compared with other nasal sprays used in the past.²³ The current study significantly extends previous results due to the prospective design, large patient population, 6 months of follow-up, and use of the formulation preferred by patients.

Outcomes registries and observational study designs as used in the BALANCE study may be important sources of real-world outcomes. The large enrollment provided by the registry format of the current study produced sufficiently robust samples to contribute data for the primary outcome variable and each of the secondary efficacy variables. Another strength of the study was the primary outcome measure, the RCAT, which was developed in accordance with the most recent U.S. Food and Drug Administration guidance for industry on PRO development.¹³ The RCAT and all other assessments have undergone the appropriate reliability and validity testing.^{10,14–17}

Limitations of this observational study must be noted. The exact patient exposure to BDP nasal aerosol could not be determined because dosage and adherence were not strictly controlled or recorded. Selection bias could limit interpretation of the study data. To decrease the impact of this potential limitation, descriptive and exploratory analyses included summaries that characterized the disposition of sites and patients, and the baseline characteristics of the starting population, the completer population, and those who were completers on BDP nasal aerosol. The lack of a minimal clinically important difference (MCID) being evaluated for the outcome measures was a limitation in the current study. Two main strategies exist for the determination of MCIDs: an anchor-based approach and a distribution-based method.²⁴

An anchor-based approach uses a study outcome with meaning that is either implicit or previously es-

tablished, thereby establishing the importance of changes as perceived by the patient. A distribution-based method relates clinical importance to the variability of a measure within the study population.²⁴ A control arm was not included, so comparisons to either placebo or an active alternative could not be made. Comparisons could be made only versus the study population baseline. It may be difficult to extrapolate data to the general population because the preponderance of study patients were female and white. Furthermore, results may not be extrapolatable out past the 6-month study duration.

CONCLUSION

Treatment with BDP nasal aerosol in the BALANCE study significantly improved PAR symptoms and measures of quality of life, work, and school-related activities from the patient's perspective under real-world conditions. In addition to supporting the use of BDP nasal aerosol, the scientific outcomes of this study should help support educational initiatives and provide additional information for clinical and managed market audiences.

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