ABSTRACT. Objective. Intranasal beclomethasone dipropionate (BDP) has generally been considered to have no systemic activity at recommended doses, but the potential for long-term effects on growth has not previously been evaluated. This study was undertaken to assess the effects of 1 year of treatment with intranasal BDP on growth in children.

Study Design. In this double-blind, randomized, parallel-group study, 100 prepubertal children 6 to 9 years old with perennial allergic rhinitis were treated with aqueous BDP 168 μg twice daily (n = 51) or placebo (n = 49) for 1 year. Subjects’ baseline heights were required to be between the 5th and 95th percentile, and skeletal age as determined by left wrist radiograph was required to be within 2 years of chronological age. Washout periods for medications known to affect growth, including other forms of corticosteroids, were established, and these medications were prohibited during the study. However, short courses of oral prednisolone lasting no more than 7 days, were allowed. Height was measured with a stadiometer after 1, 2, 4, 6, 8, 10, and 12 months of treatment (intent-to-treat principle). The rate of change in standing height was analyzed for all subjects who entered the study and for those completing the full 12 months of treatment (n = 80). The rate of change in standing height over the 1-year study was calculated as the slope of a linear regression line fitted to each subject’s height measurements over time. Because there was a statistically significant between-group difference in standing height at baseline, an analysis of covariance was performed for all analyses of standing height data.

Results. Of the 100 subjects enrolled, 90 completed the study. The 2 treatment groups were generally comparable at baseline; however, at baseline, mean age and mean height were significantly greater in the BDP treatment group that the in placebo treatment group. In both groups, overall growth rate was significantly slower in BDP-treated subjects than placebo-treated subjects. The mean change in standing height after 1 year was 5.0 cm in the BDP-treated subjects compared with 5.9 cm in the placebo-treated subjects. The difference in growth rates was evident as early as the 1-month treatment visit, suggesting that the effect on growth occurred initially.

The growth-suppressive effect of BDP remained consistent across all age and gender subgroups, and among subjects with and without a previous history of corticosteroid use. Use of additional exogenous corticosteroids during the study was similar in both groups and did not affect the results.

Because there was a baseline imbalance in height, a supplemental analysis of the differences in prestudy growth rates was performed. This analysis found no baseline imbalance in prestudy growth rates.

To determine whether the difference in growth rates during the study could be attributed to preexisting growth rates, a z score analysis was performed. The height of both groups were normalized at baseline and at the end of the study using the US National Center for Health Statistics data for mean and standard deviations of height. This analysis confirmed that the difference in growth rates between the 2 groups was primarily attributable to the treatment rather than to any preexisting difference in growth. Additional analyses confirmed that the results were not influenced by outlier values.

No significant between-group difference were found in the hypothalamic-pituitary-adrenocortical axis assessments. No unusual adverse events were observed.

No evidence of other systemic effects of BDP was found, including analysis for fluid and electrolyte imbalances; alterations in protein, lipid, or carbohydrate metabolism; alterations in formed elements in blood; and alterations in differential white blood cell counts, including eosinophils.

Conclusions. Additional study is warranted to define the clinical relevance of these findings. This study suggests, however, that intranasal BDP may slow growth rate in children without suppressing basal 6 AM cortisol concentrations or the response to cosyntropin stimulation, which are commonly used clinically to test for adrenal suppression. The effect on final height is unknown.

Alternative explanations for the finding of drug-induced growth suppression, including the possibility that the results were affected by either differences in height and age at baseline between the 2 groups or by outlier values, were discounted upon additional analysis. The results of this study were considered by the Food and Drug Administration in the development of recently proposed new class labeling for all inhaled and intranasal corticosteroids, which states that these agents may cause a reduction in growth velocity in pediatric patients (see reference 21). However, both the Food and Drug Administration and the American Academy of Pediatrics recommend that growth suppression should be measured in children receiving these medications.
Intranasally administered corticosteroids have repeatedly been shown to be effective in controlling the symptoms of allergic rhinitis in children.\(^1\)\(^,\)\(^2\)\(^,\)\(^3\) Although long-term systemic use of oral or parenteral corticosteroids in children has been associated with growth suppression and other significant adverse effects,\(^4\)\(^,\)\(^5\) intranasal corticosteroids have been considered to be relatively free of systemic effects and to be an effective treatment option for children with allergic rhinitis.\(^6\)

Beclomethasone dipropionate (BDP) aqueous nasal spray has been demonstrated to be well tolerated and effective in the treatment of rhinitis in adults and in children 6 years of age and older. The corticosteroid activity of BDP has been thought to be primarily confined to the application site, and only minimal systemic effects have been reported at recommended intranasal dosages. One study in healthy adult volunteers found that intranasal BDP 336 \text{mcg} / \text{day} for 4 days had only insignificant effects on overnight urinary cortisol excretion and on serum cortisol after adrenocorticotropic hormone (ACTH) stimulation.\(^7\)

In contrast, 24-hour urinary cortisol was significantly suppressed in another study of adult volunteers after 4 days of BDP 800 \text{mcg} / \text{day}, although there was no significant effect at lower doses of BDP.\(^8\) In this study, urinary cortisol levels of patients who had received the BDP 800 \text{mcg} / \text{day} were decreased 17% (\(P < .001\)) versus placebo.\(^8\) Other studies have failed to demonstrate any significant effects of intranasal BDP on the hypothalamic pituitary adrenal (HPA) axis.\(^9\)

No previous studies have investigated the long-term effects of intranasal BDP on growth in children. The present study was undertaken to evaluate the potential for 1 year of treatment with intranasal aqueous BDP to affect growth in children with allergic rhinitis.
and weight were recorded after 1 month and at each subsequent visit. Routine clinical laboratory tests and urinalysis were performed at screening and after 6 and 12 months, and an assessment of sexual maturity by Tanner staging was repeated at the 12-month visit.

Cosyntropin Testing
Cosyntropin stimulation testing was performed to assess HPA-axis function at screening and at the 6- and 12-month visits. At 8 AM (±1 hour), a plasma sample was taken to determine the prestimulation plasma cortisol concentration. This was followed by the intravenous or intramuscular injection of 25 mg of cosyntropin. A second plasma sample was taken to measure cortisol concentrations 60 minutes after the injection to determine adrenocortical response. At screening, the prestimulation (8 AM) plasma cortisol concentration was required to be ≥7 μg/dL and the 60-minute cosyntropin concentration was to have increased at least 7 μg/dL above the baseline value for the patient to be eligible for enrollment.

Statistics
Analyses were based on all randomized patients who received at least 1 dose of medication (intent-to-treat principle). For the primary parameter (the rate of change in standing height) additional analyses were based on the standing height data of patients who had data for each of the visits throughout the 12 months of study.

The rate of change in standing height over the 1-year study period was calculated as the slope of a linear regression line fitted to each patient’s height measurements over time. The slopes were calculated using the actual patient data, including baseline. Similar rates of change over the available pretreatment data were also calculated for each patient. Because there was a statistically significant difference in posttreatment data between groups, an analysis of covariance was performed for all analyses of standing height data, including the primary variable, with baseline height as the covariate.

Additional confirmatory analyses were performed. To perform a linear regression analysis, the heights of both groups were normalized at baseline and at the end of the study, using the US National Center for Health Statistics data for mean and standard deviations of height to determine whether differences in growth rates during the study could be attributed to preexisting growth rates. In addition, height-adjusted age and outlier values were assessed.

Plasma cortisol concentrations and body weight were analyzed by analysis of variance, including effects attributable to treatment and center, was performed for all analyses of standing height data, including the primary variable, with baseline height as the covariate.

Additional analyses were performed. For all patients who entered the study, the rate of growth in the BDP-treated patients was significantly slower than in placebo-treated patients. The mean overall rate of growth was .013 cm/day in BDP-treated patients and .017 cm/day in placebo-treated patients (P < .01). Differences between treatment groups in changes from baseline height were observed after the first month of treatment (P = .04) and also at months 6, 8, 10 and 12 (Fig 1). An analysis that excluded patients who received courses of oral corticosteroids during the course of the study found these patients to not have any significant impact on the study results.

Similar results were found in the analysis of patients who completed all 12 months of treatment. In this group of patients, the differences between treatment groups in mean changes from baseline were statistically significant at all visits from 1 month to the end of the study (P ≤ .05; Fig 2). The overall rate of growth was .014 cm/day in the BDP-treated patients and .016 cm/day in the placebo-treated patients (P < .01). At month 12, the mean change in

RESULTS
A total of 100 patients was randomized and treated in this study. An average of 12 to 13 patients (range: 3–21) was enrolled at each of the 8 centers. In general, the 2 treatment groups were comparable with respect to baseline demographic and disease characteristics (Table 1). However, the children in the BDP-treatment group were significantly older and taller than those in the placebo-treatment group (P ≤ .04). Forty-five of the BDP-treated patients and 35 of the placebo-treatment patients completed the entire 12-month course of treatment; 6 patients randomized to BDP and 14 randomized to placebo discontinued the study before completion. Reasons for treatment discontinuation are given in Table 2. At the end of treatment, 1 patient treated with BDP and 3 patients treated with placebo were no longer in stage 1 of the Tanner classification of sexual maturity. The rate of change in standing height was evaluated for all patients who participated in the study and for those who completed 12 months of treatment. Approximately 50% of the patients in each treatment group had a history of corticosteroid use (oral, inhaled, intranasal, or dermatological) within the 12 months before enrollment. Six patients in the BDP group and 7 in the placebo group reported short courses (average of 5 days each) of oral corticosteroids during the study.

Change in Rate of Growth
For all patients who entered the study, the rate of growth in the BDP-treated patients was significantly slower than in placebo-treated patients. The mean overall rate of growth was .013 cm/day in BDP-treated patients and .017 cm/day in placebo-treated patients (P < .01). Differences between treatment groups in changes from baseline height were observed after the first month of treatment (P = .04) and also at months 6, 8, 10 and 12 (Fig 1). An analysis that excluded patients who received courses of oral corticosteroids during the course of the study found these patients to not have any significant impact on the study results.

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<table>
<thead>
<tr>
<th>TABLE 1. Demographic Characteristics at Baseline</th>
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<tr>
<td></td>
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<tr>
<td>Mean age (y)</td>
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<tr>
<td>Mean skeletal age determined by radiograph (y)</td>
</tr>
<tr>
<td>Gender</td>
</tr>
<tr>
<td>Female</td>
</tr>
<tr>
<td>Male</td>
</tr>
<tr>
<td>Race</td>
</tr>
<tr>
<td>White</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>Mean height (cm)</td>
</tr>
<tr>
<td>Mean weight (lb)</td>
</tr>
<tr>
<td>Mean duration of allergic rhinitis (y)</td>
</tr>
<tr>
<td>History of corticosteroid use</td>
</tr>
<tr>
<td></td>
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</tbody>
</table>

* P ≤ .04 versus placebo.

<table>
<thead>
<tr>
<th>TABLE 2. Reasons for Treatment Discontinuation</th>
</tr>
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<tbody>
<tr>
<td>Reason</td>
</tr>
<tr>
<td>Adverse events</td>
</tr>
<tr>
<td>Did not meet protocol eligibility requirements</td>
</tr>
<tr>
<td>Did not wish to continue for reasons unrelated to the study</td>
</tr>
<tr>
<td>Noncompliance</td>
</tr>
<tr>
<td>Treatment failure</td>
</tr>
<tr>
<td>Lost to follow-up</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

* One placebo-treated patient discontinued because of adverse events at the 12-month visit. However, because data were available for all time points, this patient was included in the analysis of the rate of change in standing height.
standing height from baseline was 5.0 cm for the BDP-treated patients and 5.9 cm for the placebo-treated patients ($P < .01$).

Subgroup analyses for age, gender, and history of corticosteroid use were also performed. Age and height imbalances at baseline likely had an effect on the magnitude of the treatment difference. However, consistent with the overall results, placebo-treated patients in each of the subgroups generally grew faster than BDP-treated patients (Table 3). Among the placebo patients, no difference was noted in the growth rates of boys and girls, whereas only a slightly higher growth rate was observed for 6- to 7-year-old children, compared with 8- to 9-year-old children. A history of previous corticosteroid use (oral, inhaled, intranasal, or dermatological use in the 12 months preceding the study) in these patients was associated with a slightly lower growth rate than no history of corticosteroid use. Similar observations were noted for BDP-treated patients: there was no difference in growth rates between boys and girls, a slightly higher growth rate was observed for 6- to 7-year-old children, compared with 8- to 9-year-old children, and a history of corticosteroid use was associated with a slightly lower growth rate than no history of corticosteroid use.

Because there was a baseline imbalance in age and height, a supplemental analysis of the differences in prestudy growth rates was performed. This analysis found no baseline imbalance in prestudy growth rates ($\sim .017-.018$ cm/day or 6.2–6.6 cm/year for both treatment groups), although the rate of growth was higher than average for a population of this age (6.0 cm/year).10

Analysis of normalized heights (z score analysis) confirmed that the difference in growth rates between the placebo- and BDP-treated patients was primarily attributable to the treatment rather than to any preexisting difference in growth. Also, ages were adjusted by baseline height and compared with 12-month height median ages. Significant differences in height-adjusted age were evident. Additional analyses confirmed that the results were not influenced by outlier values.

**HPA-Axis Function**

No significant differences between treatment groups were found for either the prestimulation plasma cortisol concentrations or the response to cosyntropin stimulation at any time point. Normal prestimulation plasma cortisol concentrations and normal increases in cortisol concentrations after cosyntropin stimulation ($\geq 7 \mu g/dL$) were reported for all patients (Fig 3).

**Adverse Events**

Adverse events reported during the study were similar to those that have been observed with other intranasal corticosteroids, and most adverse events were considered by the investigators to be unrelated to treatment. Adverse events that were judged by the investigator to be related, or possibly related to treatment, were reported by 33% of patients treated with BDP and 49% of patients treated with placebo (Table 4). Treatment-related adverse events were mild to moderate in severity. Only 2 patients, both of whom were treated with placebo, discontinued treatment because of adverse events, both of which were judged by the investigator to be unrelated to treatment.

Laboratory test values were typical of those found in children with allergic rhinitis but were otherwise unremarkable. There was no evidence of any systemic effects of glucocorticoids, such as fluid and electrolyte imbalances, alterations in protein, lipid or carbohydrate metabolism, alterations in formed ele-

![Fig 1. Mean change in standing height from baseline for all patients.](image1)

![Fig 2. Mean change in standing height from baseline: patients with a minimum of 1 year on study.](image2)

![Fig 3. Mean plasma cortisol values before and after cosyntropin stimulation.](image3)
possibly related to treatment.

Considered by the investigator to be related or probably or dose (.5 of corticosteroids than other tests such as the low-
ments of the HPA-axis. However, it should be noted
dilution with .25 mg cosyntropin. Thus, growth in chil-
systemic corticosteroid effect, sufficient to slightly
This difference in growth was evident as early as 1
The present study found that treatment with intra-

d patients grew at a slower rate than the placebo-treated patients. Thus, the pos-
possibly that the results were skewed by the baseline
Treatment-related, Treatment-Emer-

TABLE 4. Incidence of Treatment-Related, Treatment-Emer-

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>BDP (n = 49)</th>
<th>Placebo (n = 51)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Epistaxis</td>
<td>10 (20)</td>
<td>13 (27)</td>
</tr>
<tr>
<td>Nasal burning</td>
<td>4 (8)</td>
<td>7 (14)</td>
</tr>
<tr>
<td>Nasal irritation</td>
<td>3 (6)</td>
<td>4 (8)</td>
</tr>
<tr>
<td>Rhinitis</td>
<td>1 (2)</td>
<td>2 (4)</td>
</tr>
<tr>
<td>Sneezing</td>
<td>0</td>
<td>5 (10)</td>
</tr>
<tr>
<td>Lacrimation</td>
<td>0</td>
<td>2 (4)</td>
</tr>
<tr>
<td>Increased appetite</td>
<td>0</td>
<td>2 (4)</td>
</tr>
<tr>
<td>Coughing</td>
<td>0</td>
<td>2 (4)</td>
</tr>
<tr>
<td>Total</td>
<td>17 (33)</td>
<td>24 (49)</td>
</tr>
</tbody>
</table>

* Considered by the investigator to be related or probably or possibly related to treatment.

DISCUSSION

The present study found that treatment with intra-
This difference in growth was evident as early as 1
because height was not monitored after the
of treatment or that catch-up growth occurred could not be
BDP was well tolerated and no other sys-
the finding of a significant reduction in the rate of
growth in children who had received intranasal BDP
for 1 year was not anticipated. However, the consis-
tency of the reduction in growth rate observed in
the various subgroup analyses could represent a subtle
systemic corticosteroid effect, sufficient to slightly
blunt growth, but insufficient to depress basal 8 AM
cortisol concentrations or responsiveness to stimula-
tion with .25 mg cosyntropin. Thus, growth in chil-
ren may be a more sensitive index of systemic
gluocorticoid effects than commonly used assess-
ments of the HPA-axis. However, it should be noted
that the HPA-axis assessments used in this study
may be less sensitive at detecting the systemic effects
of corticosteroids than other tests such as the low-
dose (.5 μg) cosyntropin stimulation test or measure-
ment of 24-hour area under the plasma cortisol
concentration–time curve.11,12

Several alternative explanations for the finding of
drug-induced growth suppression were discounted
on additional analyses. For example, there was a
difference in height between the 2 groups at base-
line—BDP-treated patients were older and taller.
The results of the height measurements were anal-
yzed by an analysis of covariance to control for this
imbalance.) The difference in baseline height sug-
gests the possibility that there may have been some
differences in expected growth rates because the
older children (8–9 years of age) in this study grew at
Few previous studies have investigated the effects
of intranasal corticosteroids on long-term growth in
children; however, short-term knemometric studies
have been conducted. Knemometry is very useful in
determining relative systemic bioavailability of dif-
ferent glucocorticoids and in defining a no effect
dose for a given corticosteroid but does not predict
the extent of suppression in intermediate- or long-
term studies. Two studies involving intranasal
budesonide (BUD) in children with allergic rhinitis
have yielded conflicting results. In the first study, a
significant reduction in lower leg growth occurred
with BUD 200 μg BID administered as a nasal aerosol
spray, during which the growth rate was reduced
from .59 mm/day during the run-in phase to .05
mm/day during treatment with BUD (n = 11).13 In
the second study, no effect on growth was seen with
BUD 200 μg (n = 14) or 400 μg (n = 13) administered
once daily via nasal dry powder inhaler.14 These
results suggest that different intranasal cortico-
steroids may have varying systemic effects when ad-
ministered at recommended dosages. Whether these
findings may reflect differences in bioavailability as
well as those inherent in different formulations of
intranasal glucocorticoids (ie, aqueous, dry powder,
and aerosol) is unknown. To date, there are no pub-
lished studies comparing the effects of different in-
tranasal corticosteroid formulations on growth.

Findings of childhood growth suppression during
treatment with exogenous corticosteroids have lead
to questions regarding whether the effect is initial or
progressive. In the present study, the difference in
growth rates between the 2 study groups was evi-
dent as early as 1 month after treatment initiation.
These results suggest that the effect on growth oc-
curred early in the study (within the first few months
of treatment) and persists throughout the study.
Findings that growth suppression by intranasal
corticosteroids can occur during short-term growth
studies also suggest that the effect on growth is an
initial one. However, the interpretation of short-term
findings in the context of long-term outcomes re-
mains under debate.15 The suppression of interme-
diate-term growth in asthmatic children by inhaled
corticosteroids has been documented.16,17 Although
the results do not necessarily apply to children with
allergic rhinitis, studies of asthmatic children treated
with inhaled corticosteroids have yielded mixed re-
results. One study of 67 children treated with inhaled
BPD 200 μg BID for 1 year has found that the growth
suppressive effect is progressive, resulting in an in-
creasing deviation of growth rates from normal val-
ues over time.16 However, another study has found
the opposite effect. In this study, 50 asthmatic chil-
dren were treated with inhaled BDP 200 μg BID for

http://www.pediatrics.org/cgi/content/full/105/2/e23
CHILDHOOD GROWTH SUPPRESSION WITH INTRANASAL BECLOMETHASONE DIPROPIONATE

30 weeks. The rate of growth was only significantly suppressed compared with the baseline run-in rate during the first 6 weeks of treatment.\textsuperscript{15} Throughout the rest of the study, growth rates were similar to those seen during the run-in period.

Whether effects on childhood growth seen in intermediate-term studies result in reduced final adult height has also come into question. The long-term effects of intranasal corticosteroids on linear growth and final height in children with allergic rhinitis have not been determined. Several studies have investigated the long-term effects on height of inhaled corticosteroid therapy for the treatment of asthma; however, these results do not necessarily apply to children with allergic rhinitis. Some studies suggest that growth in these children may be delayed but that they will eventually attain their expected adult height. In 1 study, BDP-treated children with asthma who were followed for a mean of 13.1 years achieved predicted final adult height despite delayed pubertal growth acceleration.\textsuperscript{19} This finding suggests that patients who experience a reduction in growth rate attributable to corticosteroid therapy may still achieve expected final height. However, another study in which growth was significantly suppressed by inhaled BDP found no significant catch-up growth during a 4-month washout period.\textsuperscript{18} The relevance of these findings to children with allergic rhinitis treated with intranasal corticosteroids requires additional investigation. Furthermore, whether these findings will predict outcomes in a clinical practice in which dose-titration is used and compliance and duration vary remains to be determined.

The results of the present study have previously been published as an abstract\textsuperscript{20} and have been presented to the Food and Drug Administration (FDA) Pulmonary Allergy Drugs Advisory Committee and Metabolic and Endocrinologic Drugs Advisory Committee. The results of this study were considered by the FDA in the development of recently proposed new class labeling for all inhaled and intranasal corticosteroids, which states that these agents may cause a reduction in growth velocity in pediatric patients.\textsuperscript{21} At the same time, noting the limited amount of information available, the FDA called for additional study in this area. Both the FDA and relevant professional bodies in the United States (American Academy of Allergy, Asthma and Immunology; American College of Allergy, Asthma and Immunology; American College of Chest Physicians; American Thoracic Society; and American Academy of Pediatrics) concur that, depending on disease severity, the benefits of intranasal corticosteroid therapy may outweigh the risks.\textsuperscript{22} Because the effect on final height is not known, the height of children on long-term intranasal corticosteroid therapy should be monitored periodically during treatment, using a stadiometer or similarly accurate device and should be plotted on a growth or growth velocity chart to monitor for growth suppression. Furthermore, clinicians must be alert for the possibility of drug-induced growth suppression so as not to misattribute it to growth suppression related to other causes.\textsuperscript{23–26} To minimize the risks of systemic corticosteroid exposure, including growth suppression, dose-reduction strategies (eg, allergen-avoidance measures, immunotherapy and concomitant treatment with antihistamines, or decongestants) should be considered.\textsuperscript{27} In addition, many allergic rhinitis patients also receive corticosteroids via other routes for the treatment of concomitant disorders, such as asthma or atopic dermatitis. Therefore, physicians should take into account the patient’s total corticosteroid exposure when prescribing an intranasal corticosteroid and should titrate each patient to the lowest effective dose for each route to minimize systemic exposure. Physicians also should consider each medication’s potential for systemic effects when selecting among the various available corticosteroids.

CONCLUSION

In summary, treatment with intranasal aqueous BDP 168 μg BID for 1 year in children with allergic rhinitis significantly slowed growth rate without having any effect on the HPA axis as assessed by 8 AM cortisol concentrations or the response to stimulation with .25 mg cosyntropin. However, the long-term effects of intranasal BDP on final height remain unknown.

ACKNOWLEDGMENTS

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Detection of Growth Suppression in Children During Treatment With Intranasal Beclomethasone Dipropionate


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