ABSTRACT. Objective. To compare the effects of 2 nebulizable controller asthma medications on caregiver and pediatric quality of life.

Methods. In this 52-week, randomized trial, children aged 2 to 6 years with mild to moderate persistent asthma received budesonide inhalation suspension 0.5 mg (total daily dose) once or twice daily \((n = 168)\) or cromolyn sodium nebulizer solution 20 mg 4 times daily \((n = 167)\) for 8 weeks, with dosage adjustment thereafter at the investigators’ discretion. The Pediatric Asthma Caregiver’s Quality of Life Questionnaire (PACQLQ), Compliance/Caregiver Satisfaction Questionnaire (CCSQ), Modified Child Health Questionnaire-Parent Form 50 (CHQ-PF50), and Functional Status-II(R) (FS-II(R)) Questionnaire were administered at baseline and weeks 8, 28, and 52. Global assessments of ease of asthma management and child health status were obtained from caregivers and physicians at the end of the study.

Results. Improvements from baseline in domain-specific (activities and emotional function) and total PACQLQ scores were greater at each time point (weeks 8, 28, and 52) for caregivers of patients treated with budesonide compared with caregivers of patients receiving cromolyn sodium. Only the budesonide group met the criterion for a clinically important improvement \([=0.5 unit change]\) in all PACQLQ domains by week 8, which was maintained at weeks 28 and 52. Moreover, improvements surpassed the criterion for moderate clinical importance \((1.0 unit change)\) in all PACQLQ domains for the budesonide group, but this level of improvement was only achieved in the activities domain (at week 28) for the cromolyn sodium group. Based on the CCSQ, budesonide resulted in greater caregiver satisfaction, treatment convenience, ease of use, and compliance compared with cromolyn sodium. Thus, 90.7% of caregivers in the budesonide group were “completely or very satisfied” compared with 53.4% in the cromolyn sodium group. Over half \((54.6\%)\) of caregivers in the budesonide group rated budesonide “highly or very convenient” compared with 23% for cromolyn sodium; 77% rated budesonide “extremely or very easy” to use compared with 47% for cromolyn. Adherence with daily medication regimens was reported for 76% of children in the budesonide group compared with 57% in the cromolyn sodium group. Child health status, as indicated by mean FS-II(R) scores, showed improvements from baseline in both groups at weeks 8, 28, and 52. There was a trend for these improvements to be superior in the budesonide group. Additionally, budesonide was superior to cromolyn sodium in caregiver and physician global assessments. At the end of the study, 76% of caregivers of children receiving budesonide reported asthma management to be “a great deal easier” compared with the start of the study, and 74% rated the overall health status of their child as “much better now than 1 year ago.” In contrast, only 29% and 37% of caregivers whose children received cromolyn sodium provided these respective ratings.

Conclusions. Budesonide inhalation suspension improved the quality of life for caregivers of children with asthma. Caregivers of children treated with budesonide had significantly fewer limitations in daily activities and emotional functioning compared with caregivers of children treated with cromolyn sodium nebulizer solution. The improvements in caregiver quality of life occurred earlier with budesonide compared with cromolyn sodium. Only caregivers in the budesonide group had a clinically important mean change from baseline in all PACQLQ domains by week 8. These benefits were maintained at week 52. Children treated with budesonide inhalation suspension and cromolyn sodium experienced improvements in health status, assessed using the FS-II(R). The greatest differences between treatments were seen in the disease-specific portion of the FS-II(R), which relates impairments in functional status to the child’s illness. Caregiver and physician global assessment indicated significantly better overall child health after 1 year of treatment with budesonide, supporting an improvement in health status. Clinical trials in children 4 to 16 years of age with asthma have demonstrated greater effectiveness of inhaled corticosteroids versus cromolyn sodium on several clinical measures of efficacy. Measures of asthma control in this study, reported in detail elsewhere [Lefflein et al. Pediatrics. 2002;109:866–872], also have shown greater improvements with budesonide therapy. Treatment with budesonide inhalation suspension resulted in a significantly lower mean rate of asthma exacerbations, significantly longer times to first asthma exacerbation, significantly longer times to first additional use of chronic asthma therapy, and significant improvements in asthma symptom scores and breakthrough medication use compared with cromolyn sodium therapy. Additionally, children receiving budesonide inhalation suspension experienced more symptom-free days and episode-free days compared with children receiving cromolyn sodium. Safety profiles
were similar between the 2 treatment groups. Budesonide inhalation suspension was associated with significantly greater caregiver satisfaction, convenience, ease of use, and compliance compared with cromolyn sodium nebulizer solution. This greater caregiver satisfaction and quality of life may be related to the greater asthma control achieved in children treated with budesonide therapy compared with cromolyn sodium. In addition, the convenience of once- or twice-daily dosing with budesonide inhalation suspension, compared with 3- or 4-times-daily dosing of cromolyn sodium, may decrease caregiver burden and enhance the willingness of caregivers to adhere to treatment regimens prescribed for their young children with asthma. This effect on caregiver adherence could further improve treatment effectiveness. This is the first clinical trial comparing the effects of a nebulized corticosteroid with that of an alternative nebulized therapy on quality of life in young children with asthma and their families. Compared with nebulized cromolyn sodium, budesonide inhalation suspension not only provides better overall child health status and asthma management, but greater caregiver quality of life and greater caregiver satisfaction, convenience, ease of use, and compliance. Pediatrics 2003;112:e212–e219. URL: http://www.pediatrics.org/cgi/content/full/112/3/e212; budesonide inhalation suspension, cromolyn sodium, inhaled corticosteroid therapy, nebulizer therapy, quality of life, pediatric asthma, questionnaire, Pediatric Asthma Caregiver’s Quality of Life Questionnaire.

**METHODS**

**Patients**

Patients 2 to 6 years of age with mild or moderate persistent asthma were eligible for enrollment if they had asthma symptoms more than twice weekly within 6 months of study entry, nighttime asthma symptoms more than twice monthly, at least 1 asthma exacerbation requiring systemic corticosteroids within 6 months of enrollment or at least 2 such exacerbations within 9 months of enrollment, and daily use of at least 1 long-term controller asthma medication (ie, inhaled corticosteroid, nedocromil sodium, cromolyn sodium, or an oral or inhaled bronchodilator) with periodic use of breakthrough medication within 3 months of study entry. Patients were also excluded if they had received intermittent (<14-day courses) or long-term (≥14-day courses) oral corticosteroid treatment within 15 days or 12 weeks of enrollment, respectively. Patients were also excluded if they were born prematurely, had a history of severe or unstable asthma or ventilatory assistance (except at birth), were hospitalized for treatment of airway obstruction within 30 days of study enrollment, had an upper respiratory tract infection and infectious sequelae of the lower respiratory tract within 14 days of study enrollment, or had concomitant lung disease or other significant medical conditions. The study was approved by the institutional review board at each center and was performed according to the principles of the Declaration of Helsinki. Before enrollment, written informed consent was obtained from each patient’s legal guardian.

**Study Design**

This was a randomized, open-label, parallel-group, 52-week effectiveness study conducted from September 1997 to August 1999 at 36 clinical sites in the United States (AstraZeneca LP Study DX-RES-2000). Study design and treatments have been described in detail previously. Briefly, the study began with a 2- to 3-week baseline phase. Patients with asthma symptom severity scores ≥2 (scale: 0 = no symptoms to 3 = severe symptoms) on at least 7 of 14 days before randomization and who used breakthrough medication on at least 5 of these 14 days were randomized 1:1 to
receive budesonide inhalation suspension 0.5 mg (once daily or in divided doses twice daily per investigator judgment) or cromolyn sodium 20 mg 4 times daily for 8 weeks. After 8 weeks and throughout the remainder of the trial, doses of study drug could be titrated up or down at the discretion of the investigator. Budesonide could be titrated to a maximum dose of 1.0 mg twice daily and a minimum dose of 0.25 mg once daily. The dose of cromolyn sodium could be reduced to 20 mg 3 times daily. Patients returned to the clinic 6 times (weeks 2, 8, 16, 28, 40, and 52) for evaluation and data collection.

Concomitant Therapy
Patients discontinued long-term controller asthma medications before randomization. Short-acting $\beta_2$-agonists were allowed as breakthrough medication throughout the study, and a 3- to 7-day course of systemic corticosteroids with tapering was allowed, at the discretion of the investigator, to treat asthma exacerbations. Long-term asthma medications other than systemic corticosteroids (eg, methylxanthines, slow-release oral $\beta_2$-agonists) were permitted if patients required oral or parenteral corticosteroids for ≥3 asthma exacerbations or required more than the maximum recommended dose of study drug. Patients randomized to either study drug could not receive the other as additional therapy.

Outcome Measures
Caregiver Burden, Satisfaction, and Compliance
The impact of a child’s asthma on the caregiver’s normal daily activities and emotional functioning was assessed at baseline and weeks 8, 28, and 52 using the self-administered Pediatric Asthma Caregiver’s Questionnaire (PACQLQ). The PACQLQ is a 13-item questionnaire that assesses caregiver burden with a 1-week recall period. It contains 4 items in an activities domain and 9 items in an emotional function domain. Responses are based on a 7-point scale (1 = all of the time [severe impairment] to 7 = none of the time [no impairment]). Individual items are weighted equally. Total and domain scores range from 1 to 7, with higher scores indicating a more positive response. A change of 0.5 units is the minimal difference that patients and caregivers consider important. Changes of −1.0 unit are considered of moderate importance.22–25

Caregiver satisfaction, treatment convenience, ease of use, and compliance were assessed at baseline and weeks 8, 28, and 52 with a 4-item Compliance/Caregiver Satisfaction Questionnaire (CCSQ), which was developed specifically for this study. Responses to satisfaction, convenience, and ease-of-use questions are based on 7-point Likert-type responses ranging from “completely satisfied” to “completely dissatisfied,” “highly convenient” to “extremely inconvenient,” and “extremely easy” to “extremely difficult,” respectively, with 1 being the most positive response.

Child Health Status
Child health status was assessed at randomization and weeks 8, 28, and 52 using the Modified Child Health Questionnaire-Parent Form 50 (CHQ-PF50) and the Functional Status-II(R) Questionnaire (FS-II[R]). The CHQ-PF50 was self-administered by the caregiver and the FS-II(R) was administered via interview. The CHQ-PF50 is a validated measure of physical and psychosocial well-being of children using 14 multi-item scales and is reported by the caregiver. It is a 50-item generic health status questionnaire with a 4-week recall. Only the General Health Perceptions scale (5 items) was included in this study. Caregivers indicate how true or false the 5 statements in the General Health Perception scale are based on a 5-point Likert-type response scale in which graded responses are scored from 1 = definitely false to 5 = definitely true. Total score for the General Health Perceptions scale was calculated and transformed to a scale of 0 to 100, with higher scores indicating a more favorable response.

The short 14-item form of the FS-II(R) provides a non-disease-specific, concise measure of the health status of a child and determines whether specific behaviors are attributable to illness from the perspectives of the caregiver. Part 1 of the questionnaire (FS-II[R] general score) probes the child’s eating and sleeping patterns, mood, attention, energy, and behavior. Each question has 3 response options (0 = never or rarely; 1 = sometimes; and 2 = almost always). Part 2 of the questionnaire (FS-II[R] specific score) probes if the dysfunction is attributable to illness. Responses are based on a 3-point scale (0 = not at all; 1 = partly; and 2 = fully), with the specific and general scores range from 1 to 7, with higher scores representing a more positive response.

Global Assessments
Global assessments were conducted at week 52 and included 2 questions for caregivers evaluating their ability to manage the child’s asthma and overall child health status since the start of the study. Caregivers were asked to compare their ability to manage the child’s asthma at week 52 with their ability at the start of the study. Responses were based on a Likert-type scale ranging from “a great deal easier asthma management” to “a great deal more difficult asthma management.” Caregiver perceptions of the child’s health were evaluated based on responses to the question of how their child’s health was now compared with 1 year ago. Likert-type responses ranged from “a great deal better” to “a great deal worse.”

Statistical Analysis
Data were analyzed using an all-patients-treated approach, which included all randomized patients who received at least 1 dose of study medication and who had at least 1 postdose observation. Two approaches were taken to analyze data derived from the PACQLQ, FS-II(R), and CHQ-PF50 questionnaires: first, and primarily, an analysis of all observed data were performed with the last value carried forward to subsequent time points for patients who had withdrawn early or who had missing data. Second, if a patient took an additional chronic asthma medication in addition to the study medication, data were used only to the point that the additional chronic asthma medication was taken (ie, the data were censored) and, thereafter, were carried forward to subsequent time points. For all other questionnaires, an analysis of all observed data was performed with the last value carried forward to subsequent time points for patients who withdrew early or who had missing data.

Changes from baseline to each time point in total and domain-specific PACQLQ scores, FS-II(R) general and specific scores, and the CHQ-PF50 General Health Perceptions score were compared between treatment groups using an analysis of covariance (ANCOVA) model, adjusted for baseline and the fixed factors of center and treatment.27,28 Standard model diagnostics were evaluated, including an investigation of the homogeneity of treatment effects across centers and baseline scores. Significant baseline-by-treatment interactions were described by estimating mean treatment effects at several different baseline levels, using an ANCOVA model as described above, but with the inclusion of a baseline-by-treatment interaction term to allow for a different response-versus-baseline slope for each treatment group.

Global assessments were conducted at week 52 and included 2 questions for caregivers evaluating their ability to manage the child’s asthma and overall child health status since the start of the study. Caregivers were asked to compare their ability to manage the child’s asthma at week 52 with their ability at the start of the study. Responses were based on a 3-point scale ranging from “a great deal easier asthma management” to “a great deal more difficult asthma management.” Caregiver perceptions of the child’s health were evaluated based on responses to the question of how their child’s health was now compared with 1 year ago. Likert-type responses ranged from “a great deal better” to “a great deal worse.”

RESULTS
Patient Population
Of the 426 patients enrolled in this 52-week study, 335 were randomized to receive budesonide inhalation suspension ($n = 168$) or cromolyn sodium nebulizer solution ($n = 167$). Baseline demographics, asthma characteristics, and PACQLQ, CHQ-PF50, and FS-II(R) scores were similar between the treatment groups (Table 1). A total of 287 patients completed the study, 154 (92%) in the budesonide group and 133 (80%) in the cromolyn sodium group. Of the 34 patients who discontinued study treatment in the
cromolyn sodium group, 3 discontinued because of disease deterioration; 1 because of adverse events; 20 for other reasons (ie, withdrawal of consent, non-compliance with study procedures, randomization error, patient relocation); and 10 were lost to follow-up. There were no discontinuations attributable to disease deterioration or adverse events in the budesonide group, but 8 patients discontinued for other reasons and 6 patients were lost to follow-up.

**Caregiver Burden, Satisfaction, and Compliance**

Improvements in domain-specific (activities and emotional function) and total PACQLQ scores were significantly greater in the budesonide group than in the cromolyn sodium group at all time points (Fig 1A–1C and Table 2). The benefits of both treatments generally reached a maximum at week 28, and this effect was maintained at the last visit (week 52).

Mean improvements from baseline in total and domain-specific PACQLQ scores were clinically important (≥0.5 unit change) at all time points in caregivers of children receiving budesonide. Improvements surpassed the level of moderate clinical importance (1.0 unit change) by week 8 in the activities domain and by week 28 in both PACQLQ total and emotional function domain scores. In contrast, PACQLQ improvements in caregivers of children receiving cromolyn sodium reached the level of minimal clinical importance by week 8 only in the activities domain. With the exception of week 28 in the activities domain, mean changes did not reach the level of moderate clinical importance with cromolyn sodium.

For both treatments, there was a strong negative correlation between the baseline PACQLQ score and degree of improvement, such that caregivers expressing the greatest degree of burden at baseline (ie, a low score) were associated with larger improve-
TABLE 2. Mean Changes From Baseline and Treatment Differences in PACQLQ and FS-II(R) Scores at Week 52

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Treatment Group</th>
<th>N</th>
<th>Mean Score*</th>
<th>Adjusted Mean Change†</th>
<th>Difference from CSNS [95% CI]‡</th>
<th>P vs CSNS</th>
</tr>
</thead>
<tbody>
<tr>
<td>PACQLQ primary analysis</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Total score</td>
<td>CSNS</td>
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<td>Activities score</td>
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<td>1.15</td>
<td>[0.15, 0.60]</td>
<td>.004</td>
</tr>
<tr>
<td>Emotional function score</td>
<td>CSNS</td>
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<td>5.92</td>
<td>1.39</td>
<td>[0.14, 0.74]</td>
<td>.002</td>
</tr>
<tr>
<td>BIS</td>
<td>166</td>
<td>6.0</td>
<td>0.68</td>
<td>0.35</td>
<td>[0.14, 0.57]</td>
<td></td>
</tr>
<tr>
<td>PACQLQ censored analysis</td>
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<tr>
<td>Total score</td>
<td>CSNS</td>
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<td>5.44</td>
<td>0.62</td>
<td>0.47</td>
<td>&lt;.001</td>
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<tr>
<td>Activities score</td>
<td>CSNS</td>
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<td>5.24</td>
<td>0.72</td>
<td>0.60</td>
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<tr>
<td>Emotional function score</td>
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<td>5.53</td>
<td>0.57</td>
<td>0.42</td>
<td>.001</td>
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<tr>
<td>BIS</td>
<td>161</td>
<td>6.0</td>
<td>0.99</td>
<td>[0.18, 0.65]</td>
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<td>FS-II(R) primary analysis</td>
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<td></td>
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<tr>
<td>General score</td>
<td>CSNS</td>
<td>159</td>
<td>81.7</td>
<td>7.87</td>
<td>1.86</td>
<td>.216</td>
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<tr>
<td>Specific score</td>
<td>CSNS</td>
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<td>85.9</td>
<td>7.58</td>
<td>[−1.09, 4.81]</td>
<td>.055</td>
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<tr>
<td>BIS</td>
<td>166</td>
<td>84.1</td>
<td>9.73</td>
<td>[−0.06, 6.23]</td>
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<tr>
<td>General score</td>
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<td>Specific score</td>
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<td>BIS</td>
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<td>89.8</td>
<td>10.98</td>
<td>[2.72, 9.28]</td>
<td></td>
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</tbody>
</table>

CSNS indicates cromolyn sodium nebulizer solution; BIS, budesonide inhalation suspension.
* Higher scores indicate a more positive response.
† Adjusted mean change from baseline from ANCOVA model.
‡ 95% confidence interval of the treatment difference from ANCOVA model.

...ments from baseline than those with a lesser degree of burden at baseline. The strength of this relationship differed between the 2 treatments, as evidenced by a significant baseline-by-treatment interaction in the ANCOVA model. When mean changes from baseline in PACQLQ scores were estimated based on the degree of caregiver burden at baseline and compared between treatments, the largest difference between treatment groups was observed in caregivers with the lowest baseline PACQLQ scores (ie, greater burden). For example, the mean difference between the budesonide and cromolyn sodium groups in PACQLQ total score at week 52 was 1.07 (95% confidence interval [CI]: 0.47–1.66), surpassing the threshold for moderate clinical importance, when estimated at a baseline score of 2 (very burdened) compared with 0.08 (95% CI, −0.24–0.41) when estimated at a baseline score of 6 (hardly burdened).

Analysis of PACQLQ data censored at the time of initiation of additional chronic asthma medication led to the same conclusions as the primary analysis, but the effect of this adjustment was to decrease mean changes from baseline in the cromolyn sodium group while not substantially altering responses in the budesonide group. As a result, in this additional analysis, mean differences between budesonide and cromolyn sodium were even larger than in the primary analysis, and they approached or exceeded the threshold for minimal clinical importance. Censored PACQLQ data at week 52 are shown in Table 2.

Mean scores for caregiver satisfaction, convenience, ease of use, and compliance, based on the CCSQ, were significantly (P ≤ .001) greater for those caregivers whose children received budesonide versus cromolyn sodium. Most caregivers whose children received budesonide (90.7%) were “completely or very satisfied” compared with only about half of those whose children received cromolyn sodium (53.4%) (Fig 2A). Additionally, 54.6% of caregivers rated budesonide “highly or very convenient” compared with only 23% for cromolyn sodium (Fig 2B). Seventy-seven percent of caregivers rated budesonide “extremely easy” or “very easy” to use compared with only 47% for cromolyn sodium. In the budesonide group, 76% of caregivers reported that their children took their medication daily compared with 57% of caregivers in the cromolyn sodium group.

Child Health Status

Child health status, based on mean FS-II(R) scores, improved from baseline to weeks 8, 28, and 52 in both treatment groups (Table 2), but to a somewhat greater extent in children receiving budesonide. Health status generally improved at each successive visit, and improvements were greater for specific versus general scores. Differences between treatment groups in specific scores approached statistical significance at both weeks 8 and 52.

Similar to the PACQLQ, additional analysis of censored data from the FS-II(R) demonstrated greater differences between treatments than in the primary analysis, such that mean differences between treatment groups in both general and specific scores were statistically significant at all time points (Table 2). As in the primary analysis, differences were greater in FS-II(R) specific scores.

Mean CHQ-PF50 scores decreased slightly from...
Global Assessments

Global assessment by caregivers demonstrated significantly (P ≤ .001) easier asthma management with budesonide versus cromolyn sodium at study end (week 52). A majority of caregivers of children receiving budesonide (76%) reported asthma management to be “a great deal easier” at study end compared with fewer caregivers of children receiving cromolyn sodium (29%).

Global assessment of child health status by caregivers also significantly (P ≤ .001) favored budesonide over cromolyn sodium. Twice as many caregivers of children receiving budesonide (74%) than caregivers of children receiving cromolyn sodium (37%) rated overall child health status as “much better now than 1 year ago.”

DISCUSSION

This 52-week study compared the impact of treatment with budesonide inhalation suspension or cromolyn sodium nebulizer solution on the quality of life of caregivers of children with persistent asthma as well as on the children’s functional health status and day-to-day activities. The data demonstrate that caregivers of children treated with budesonide inhalation suspension have significantly fewer limitations in PACQLQ-related daily activities and emotional functioning compared with caregivers of children treated with cromolyn sodium nebulizer solution. Treatment with budesonide improved caregivers’ quality of life earlier than treatment with cromolyn sodium. Only caregivers of children in the budesonide group had a clinically important mean change from baseline (≥0.5 units) in all PACQLQ domains by week 8 and improvement >1.0 in all PACQLQ domains by week 28; these benefits were maintained at week 52.

For both treatments, there was a strong negative correlation between the baseline PACQLQ score and degree of improvement, such that caregivers expressing the greatest degree of burden at baseline (ie, a low score) were associated with larger improvements from baseline than those with a lesser degree of burden at baseline. It is not certain if this is truly a pharmacologic effect or rather an artifactual “floor effect” of the questionnaire caused by a subgroup of caregivers with relatively high baseline scores who had no room for improvement. This pattern of responses has been reported previously with different therapies and a different quality-of-life instrument.31

Budesonide provided significantly greater caregiver satisfaction, treatment convenience, ease of use, and compliance than cromolyn sodium. The results of this study are not unexpected because once- or twice-daily dosing has been previously associated with improved patient compliance and willingness to use controller therapy compared with 4-times-daily dosing.32,33

Coincident with this positive impact on caregiver quality of life, the present study has shown improve-

Fig 2. Caregivers’ responses to the satisfaction (a) and convenience (b) questions of the CCSQ. The bars depict the percentage of caregivers providing responses in each Likert-type category at week 52 (numbers for percentages <5 are not shown). Categories for “very” and “completely” satisfied/convenient and “very” and “completely” dissatisfied/inconvenient were combined in the figures to reduce the scale from 7 to 5 categories; however, a 7-point scale was used for the ANCOVA analysis of mean results. Mean scores adjusted for center and baseline effect appear on the top of each bar, with lower numbers indicating a more positive response. Estimated mean differences between treatments and associated 95% CIs appear above the brackets. BIS (budesonide inhalation suspension), (n = 161); CSNS (cromolyn sodium nebulizer solution), (n = 148). *P ≤ .001 versus CSNS.

baseline in the budesonide (−5.5) and cromolyn sodium (−5.1) treatment groups by week 52. Differences between treatments were not significant (P = .635), and unlike PACQLQ and FS-II(R) scores, adjusting for additional asthma medications did not increase treatment differences.
ment in functional status of children receiving both budesonide and cromolyn sodium using the FS-II(R). The greatest differences between treatments were seen in Part II of the FS-II(R), which relates impairments in functional status to the child’s illness. Important, was the additional finding of greater between-treatment differences in FS-II(R), as well as PACQLQ, scores when data were censored for additional use of chronic asthma medications. Results of the censored analyses provide a more accurate reflection of differences attributable solely to the study drugs. The fact that improvement in functional status was not seen with the CHQ-PF50 may reflect less sensitivity of the General Health Perceptions scale to treatment effects in asthmatic patients with minimal impairment.

Greater improvements in health status with budesonide versus cromolyn were supported by global assessment indicating significantly better asthma management and overall child health after 1 year of treatment.

In general, clinical trials in children 4 to 16 years of age with asthma have demonstrated greater effectiveness of inhaled corticosteroids versus cromolyn sodium on typical clinical measures of efficacy. Greater improvements in health status with budesonide versus cromolyn were supported by global assessment indicating significantly better asthma management and overall child health after 1 year of treatment.

This is the first clinical trial comparing the effects of a nebulized corticosteroid with that of an alternative nebulized therapy on quality of life in young children with asthma and their families. Compared with nebulized cromolyn sodium, budesonide inhalation suspension not only provides better overall child health status and asthma management, but greater caregiver quality of life and greater caregiver satisfaction, convenience, ease of use, and compliance.

ACKNOWLEDGMENTS

This work was supported in part by AstraZeneca LP. We thank Leslie Sell, PhD, and Michael McNamara, MS, for their assistance in the preparation of this manuscript.

This study was conducted by the Budesonide Inhalation Nebulizer Suspension Study Group, consisting of the following investigators: James W. Baker, MD (Portland, OR); Michael S. Blair, MD (Memphis, TN); David A. Brown, MD (Asheville, NC); Donald Bukstein, MD (Madison, WI); Bradley E. Chips, MD (Sacramento, CA); Robert Cohen, MD (Lawrenceville, GA); Howard Eigen, MD (Indianapolis, IN); Mark Ellis, MD (Orange, CA); Stanley P. Galant, MD (Orange, CA); David Geller, MD (Orlando, FL); Pinkus Goldberg, MD (Indianapolis, IN); Evalyn N. Grant, MD (Chicago, IL); Anne-Marie Irani, MD (Richmond, VA); Charles G. Jackson, MD (Kirkland, WA); Robert L. Jacobs, MD (San Antonio, TX); Michael Kaplan, MD (Los Angeles, CA); Michael J. Kraemer, MD (Spokane, WA); Jeffrey G. Lefleif, MD (Ann Arbor, MI); Bruce Martin, MD (San Antonio, TX); Michael Mellon, MD (San Diego, CA); Louis Mendelson, MD (West Hartford, CT); Gerald C. Moore, MD (Plano, TX); Kevin Murphy, MD (Omaha, NE); David Pearlman, MD (Aurora, CO); Andrew J. Pedinoff, MD (Princeton, NJ); Gary Rachelesky, MD (Los Angeles, CA); Michael Ruif, MD (Dallas, TX); Barbara J. Sanders, MD (Littleton, CO); Gail Shapiro, MD (Seattle, WA); Jerry M. Shier, MD (Rockville, MD); Howard I. Silk, MD (Atlanta, GA); David P. Skoner, MD (Pittsburgh, PA); Joseph Sproviero, MD (Norwalk, CT); F. McDaniel Atkins, MD (Denver, CO); Melanie Gleason, PA (Denver, CO); Stanley J. Szeffler, MD (Denver, CO); Michael Welch, MD (San Diego, CA); and Richard Wyatt, MD (Minneapolis, MN).

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Effects of Budesonide Inhalation Suspension Compared With Cromolyn Sodium Nebulizer Solution on Health Status and Caregiver Quality of Life in Childhood Asthma

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*Pediatrics* 2003;112;e212

DOI: 10.1542/peds.112.3.e212

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Kevin R. Murphy, Sherahe Fitzpatrick, Mario Cruz-Rivera, Christopher J. Miller and Bhash Parasuraman

*Pediatrics* 2003;112:e212

DOI: 10.1542/peds.112.3.e212

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