

Effectiveness of Oral or Nebulized Dexamethasone for Children With Mild Croup

Joseph W. Luria, MD; Javier A. Gonzalez-del-Rey, MD; Gregg A. DiGiulio, MD; Constance M. McAneney, MD; Jennifer J. Olson, MD; Richard M. Ruddy, MD

Objective: To assess the efficacy of oral dexamethasone or nebulized dexamethasone sodium phosphate in children with mild croup.

Methods: Double-blind, placebo-controlled study of 264 children between 6 months and 6 years of age with symptoms of croup for fewer than 48 hours. Patients were excluded if they received racemic epinephrine or corticosteroid treatment during the 14 days prior to enrollment or complicating medical condition. Subjects randomly received oral dexamethasone (0.6 mg/kg), nebulized dexamethasone sodium phosphate (160 µg), or placebo. Telephone follow-up was obtained on days 1, 2, 3, 4, and 7.

Main Outcome Measures: The primary outcome measure was treatment failure, defined as receiving corticosteroid or racemic epinephrine treatment during the 7 days after enrollment in the study. Secondary outcome measures included seeking additional care and the parental assessments of the patients' condition obtained during follow-up (worse, same, better, or gone).

Results: Eighty-five patients received oral dexamethasone, 91 received nebulized dexamethasone, and 88 received placebo. There were 3 treatment failures in the oral dexamethasone-treated group, 12 in the nebulized dexamethasone-treated group, and 10 in the placebo-treated group ($P=.05$). Ten children in the oral dexamethasone-treated group sought additional care compared with 27 and 29 in the nebulized dexamethasone-treated and placebo-treated groups, respectively ($P=.002$). Parents of children in the oral dexamethasone-treated group reported greater improvement on day 1 ($P<.001$) compared with the nebulized dexamethasone-treated and placebo-treated groups.

Conclusions: Children with mild croup who receive oral dexamethasone treatment are less likely to seek subsequent medical care and demonstrate more rapid symptom resolution compared with children who receive nebulized dexamethasone or placebo treatment.

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From the Division of Emergency Medicine, Children's Hospital Medical Center, Cincinnati, Ohio (Drs Luria, Gonzalez-del-Rey, DiGiulio, McAneney, and Ruddy); and the Section of Emergency Medicine, Mayo Eugenio Litta Children's Hospital, Mayo Clinic, Rochester, Minn (Dr Olson).

CORTICOSTEROIDS are commonly prescribed for the treatment of acute viral laryngotracheobronchitis (croup). Much of the evidence that supports this practice is derived from patients with more severe disease. This includes outpatient investigations in which a substantial number of patients received treatment with nebulized epinephrine^{1,2} and inpatient studies.³⁻⁵ Recently, Geelhoed et al⁶ reported that patients with mild croup are less likely to seek additional care if treated with a single dose of oral dexamethasone.

Despite evidence supporting the use of nebulized budesonide in the treatment of croup,⁷⁻⁹ we identified only 1 published study examining the effectiveness of nebulized dexamethasone sodium phosphate.¹⁰ The authors reported that patients treated with nebulized dexamethasone demon-

strated greater clinical improvement at 4 hours compared with patients receiving placebo. There was no evidence of a sustained clinical effect and 2 patients in the treatment arm developed significant complications.

The study herein determined whether administration of oral or nebulized dexamethasone decreases the need for subsequent treatments, shortens symptom duration, or decreases the need for subsequent care in children with croup of mild severity. The study also addresses the need for additional information regarding the effectiveness of corticosteroids for treating patients with mild disease.

RESULTS

Two hundred sixty-four patients were enrolled in the study. Eighty-five patients were in the oral dexamethasone-treated

PATIENTS AND METHODS

PATIENTS

The study population consisted of patients presenting to the emergency departments (EDs) at either Children's Hospital Medical Center, Cincinnati, Ohio, or Children's Hospital, Columbus, Ohio, from September 1, 1995, through December 31, 1997. The study institutions are large urban tertiary care centers. Each ED has approximately 80000 patient visits annually.

Patients eligible for the study were 6 months to 6 years old presenting with a syndrome of barking cough, stridor, and/or hoarseness for fewer than 48 hours. In an attempt to exclude patients with spasmodic croup, the presence of a viral prodrome consisting of fever, cough, or rhinorrhea was required for study participation.

Patients were excluded if they had been treated with corticosteroids during the 14 days prior to enrollment or if they had severe disease. Severe disease was defined as any patient who received nebulized racemic epinephrine or corticosteroids at the order of the treating ED physician or had an oxygen saturation rate of less than 94%. Patients were similarly excluded if they had a clinical picture consistent with spasmodic croup, a history of prolonged endotracheal intubation, a history of chronic respiratory illness (ie, asthma or cystic fibrosis), a condition associated with airway abnormalities (ie, Pierre Robin or trisomy 21 syndrome), or did not have a working telephone.

Informed written consent was obtained for eligible patients who agreed to participate in the study. Consent was obtained by attending ED physicians or fellows. The ED physicians and fellows were familiarized with the study protocol and consent process prior to initiating the study.

After informed consent was obtained, demographic, historical, and family data were recorded. This included the duration of the child's croup symptoms, whether the child had a history of croup, whether the parent had ever cared for a child with croup, if there were smokers in the home, and if the family had access to a humidifier and/or vaporizer. Subsequent to the collection of this information, a croup

score (**Table 1**) was calculated and a nasopharyngeal viral culture was obtained.

The croup score used in the study was a modification of the system employed by Westley et al.¹¹ Specifically, the stridor section of the score was altered to include 1 point if the subject had stridor only with agitation or excitement. The Westley et al.¹¹ scoring system was designed to evaluate patients over a broad range of severity. Since the patients in this study had mild croup, a score of 0 for air entry, cyanosis, and level of consciousness was expected. Croup scores were assigned solely to describe symptom severity at enrollment. After examining the other 2 portions of the score, stridor and retractions, we believe our modification was necessary to more accurately describe disease severity in the study population.

Subjects were then block randomized in a double-blind fashion to 1 of 3 treatment groups. The randomization was performed in blocks of 15 by the study pharmacist at each enrolling site with the use of a random number generator. The study pharmacist then assembled numbered "croup kits" containing study preparations that reflected the results of the randomization. The kits were sealed to prevent any tampering and were kept in the EDs. The study physician retrieved the lowest numbered kit when enrolling a new subject to maintain the randomization order. Only the study pharmacists knew the results of the randomization.

The first treatment group received 0.6 mg/kg of oral dexamethasone (maximum dose, 10 mg) and nebulized placebo. Dexamethasone Intensol (Roxane Laboratories Inc, a subsidiary of Boehringer Ingelheim Crop, Ridgefield, Conn), a 1-mg/mL solution, was used as the oral treatment. The second group received oral placebo and 160 µg of nebulized dexamethasone sodium phosphate. The third group received both oral and nebulized placebo. All oral study preparations were mixed 1:1 with a commercially available grape flavoring to minimize taste bias. Nebulized study preparations were delivered via a nebulizer (Airlife, Misty-Neb Nebulizer; Allegiance Healthcare Corp, McGaw Park, Ill) with a fill volume of 3 mL and oxygen flow set at 5 to 6 L/min.

Continued on next page

group, 91 patients in the nebulized dexamethasone-treated group, and 88 in the placebo-treated group. It was discovered that 9 patients did not meet enrollment criteria after entering the study. These patients were included in keeping with the intention-to-treat study design. Six of the 9 patients had croup symptom duration of longer than 48 hours. Two had a history of chronic pulmonary illness (asthma) and 1 had a history of prolonged endotracheal intubation.

Two hundred twenty-one patients (84%) were available on day 7 (**Table 2**). The hospital and outpatient records of the 43 patients who were unavailable 1 week after enrollment were reviewed. The records indicate that 14 of these patients returned to either the ED or their primary care physician's office. Twenty-nine of the 43 children returned to neither the enrolling ED nor their primary care physician. Only data obtained during telephone encounters with these 29 patients' data were included. Otherwise these data were considered missing.

There was no significant difference between the 3 groups for age, sex, symptom duration, or croup score (**Table 3**). Similarly, there was no difference in the viral isolates recovered from the patients (**Table 4**).

There were 3 (4%) treatment failures in the oral dexamethasone-treated group (**Figure**). This compares with 12 (16%) and 10 (14%) treatment failures in the nebulized dexamethasone-treated and placebo-treated groups, respectively ($P = .05$). Based on the sample size, the study had 58% power to detect the observed difference in treatment failures. Twenty of the treatment failure patients returned for additional care and received corticosteroids within 2 days of enrollment. The other 5 treatment failure patients received corticosteroids 3 to 4 days after enrollment. Seventeen of the treatment failure patients presented to the ED for their subsequent care. The other 8 patients received corticosteroids at the primary care physician's office.

Based on the treatment failure rates observed in the oral dexamethasone-treated and placebo-treated groups, a number needed to treat was calculated. A practitioner

After the study treatments were administered, patients were discharged home if the treating ED physician did not believe further treatment or observation was warranted. Prior to discharge, all parents were given pre-printed information about croup including strategies for home management. The information sheet also contained a telephone number that caregivers could call if they desired medical advice. Medical advice calls were answered by 1 of the investigators who was available 24 hours a day, 7 days a week.

Telephone follow-up was obtained on days 1, 2, 3, 4, and 7 after enrollment. During each follow-up encounter caregivers were asked to provide a global assessment of their child's croup symptoms (ie, worse, same, better, or gone) compared with their condition in the ED.² Parents were also asked whether they had called a health care professional for medical advice or sought additional medical evaluation since enrollment or the last follow-up encounter. The office and/or hospital medical records of patients who sought additional care were reviewed to determine the severity of croup symptoms at that time as well as any treatments that were prescribed.

The hospital and primary care medical records of all patients who did not complete follow-up were also reviewed to determine if they had returned for subsequent care. These medical records were used to determine the reason these children returned for care, the severity of any croup symptoms, and whether any new treatments were prescribed.

The primary outcome measure was treatment failure, defined as a physician reevaluating a patient's condition and prescribing corticosteroids or racemic epinephrine. Secondary outcome measures included whether the child presented for additional medical care and the parental assessments of the patients' condition obtained during telephone follow-up.

The study design was based on an intention-to-treat model. Data from patients who refused or vomited oral dexamethasone were included in the oral dexamethasone-treated group. Similarly, data from patients who were combative during the administration of nebulized dexamethasone were included in the nebulized dexamethasone-treated group.

The study protocol did not allow for a second dosing of the oral or nebulized dexamethasone treatments.

To further quantify the relationship between corticosteroid exposure and subsequent treatment failure, the number needed to treat was calculated.¹² In this study, the number needed to treat estimates the number of children a clinician would have to treat with corticosteroids to prevent 1 patient from returning with clinically significant croup.

STATISTICAL ANALYSES

The χ^2 test was used to analyze all categorical data. Analysis of variance was applied to continuous normally distributed data and the Kruskal-Wallis test was used to evaluate nonnormally distributed data. Statistical significance was set at a $P < .05$. Pairwise analyses of outcome measures were also performed. For pairwise comparisons, the χ^2 test was used to analyze all categorical data and the Mann-Whitney test was applied to continuous nonnormally distributed data. Statistical significance for the pairwise comparisons was set at $P < .02$. SPSS 10.0 software (SPSS, Chicago, Ill) was used for all statistical analyses. The investigational review boards at each of the participating hospitals approved this study.

SAMPLE SIZE

At the time of the study, we could not identify any published data estimating the percentage of untreated children with mild croup who subsequently require additional follow-up or treatment with corticosteroids. Therefore, we did not use our primary outcome measure to calculate the sample size of the study. Pilot data indicated that croup symptoms generally resolve within 4 days. To detect a 25% reduction in symptom duration between those patients treated with corticosteroids and those not receiving treatment, at least 50 patients were required in each treatment arm assuming an α level of .05 and power of 80%. Since the sample size calculation was not based on the study outcome measures, a post hoc power calculation was performed.

would need to treat 10 patients (95% confidence interval, 9-11 patients) with oral dexamethasone to prevent 1 from returning with croup severe enough to warrant corticosteroid administration.

Ten children (13%) in the oral dexamethasone-treated group sought a second medical evaluation during the 7 days following enrollment. This compares with 27 (33%) in the nebulized dexamethasone-treated group and 29 (37%) in the placebo-treated group, respectively ($P = .002$). Of the children who sought additional medical evaluation, 7 (9%) in the oral dexamethasone-treated group returned specifically because of concerns regarding croup symptoms. This compares with 19 patients (24%) in the nebulized dexamethasone-treated group and 18 patients (24%) in the placebo-treated group ($P = .03$) (Figure).

Parents were asked during each follow-up call if their child's croup symptoms were worse, the same, better, or gone. These responses were assigned a score of 1, 2, 3, or 4, respectively. For each follow-up telephone encoun-

ter (days 1, 2, 3, 4, and 7), the scores of individual subjects were ranked. The mean ranks of the children in each treatment arm were then compared. The scores of the children in the oral dexamethasone-treated group were significantly better than those in the nebulized dexamethasone-treated and placebo-treated groups on day 1 ($P < .001$). There was no difference in the caregiver reports for days 2, 3, 4, or 7.

Pairwise comparisons revealed no statistical differences in treatment failure rates between the 3 groups. Statistical differences were noted between the oral dexamethasone-treated and placebo-treated groups with respect to seeking subsequent care and returning for care specifically owing to croup symptoms ($P = .001$ and $P = .014$, respectively). Similar differences were found between the oral and nebulized dexamethasone-treated groups ($P = .003$ and $P = .01$, respectively). Caregivers of children in the oral dexamethasone-treated group reported greater clinical improvement in croup symptoms on day 1 ($P < .001$) compared with the placebo-treated group. Children in the oral

Table 1. Croup Scoring System

Indicator of Disease Severity	Score
Stridor	
None	0
Only with agitation or excitement	1
At rest with stethoscope*	2
At rest without stethoscope*	3
Retractions	
None	0
Mild	1
Moderate	2
Severe	3
Air entry	
Normal	0
Decreased	1
Severely decreased	2
Cyanosis	
None	0
With agitation	4
At rest	5
Level of consciousness	
Normal	0
Altered mental status	5

*At rest with stethoscope indicates stridor can only be heard using a stethoscope; at rest without stethoscope, stridor so loud it can be heard without using a stethoscope.

dexamethasone-treated group also demonstrated greater clinical improvement on day 1 ($P = .002$) and day 2 ($P = .005$) compared with the nebulized dexamethasone-treated group. There was no difference between the nebulized dexamethasone-treated and placebo-treated groups with respect to returning for subsequent care, returning for care specifically owing to croup symptoms, or the caregiver reports.

COMMENT

In our study, children with mild croup benefited from a single 0.6-mg/kg dose of oral dexamethasone compared with 160 μg of aerosolized dexamethasone sodium phosphate or placebo. In 1996, Geelhoed et al⁶ published the results of a study in which patients with mild croup were treated with either oral dexamethasone (0.15 mg/kg) or placebo. In that study, none of the patients who received dexamethasone treatment and 17% of the patients who received placebo subsequently presented for ongoing croup symptoms. By comparison, 9% of those who received oral dexamethasone and 24% of those who received placebo in our study sought additional care because of their croup symptoms. It is difficult to ascertain the reason we observed a modestly higher rate of return among dexamethasone-treated patients. Our larger sample size, younger study population, intention-to-treat model, and the fact our study population presented with somewhat more severe symptoms may have contributed to this.

In another outpatient study, Cruz et al² administered intramuscular dexamethasone (0.6 mg/kg) or placebo to patients with moderate croup. They reported that 84% of the dexamethasone-treated patients and 42% of those in the placebo group reported improvement in croup symptoms 24 hours after enrollment. Our results were

Table 2. Summary of Patient Follow-up*

Follow-up Day	Oral Treatment Group (n = 85)	Nebulized Treatment Group (n = 91)	Placebo Treatment Group (n = 88)
1	80 (94)	81 (89)	79 (90)
2	80 (94)	80 (88)	76 (86)
3	77 (91)	78 (86)	75 (85)
4	75 (88)	74 (81)	73 (83)
7	73 (86)	77 (85)	71 (81)

*Oral treatment group indicates those who received 0.6 mg/kg of oral dexamethasone and nebulized placebo (ie, a 1-mg/mL solution of Dexamethasone Intensol; Roxane Laboratories Inc, subsidiary of Boehringer Ingelheim Corp, Ridgefield, Conn); nebulized treatment group, those who received oral placebo and 160 μg of nebulized dexamethasone sodium phosphate; placebo treatment group, those who received oral and nebulized placebo. All data are given as number (percentage) of patients.

similar despite our subjects having less severe disease. In our study, 83% of the patients treated with oral dexamethasone and 56% of the subjects in the placebo group reported improvement 24 hours after enrollment.

When assessing the validity of this study, a number of factors require consideration. The first is our choice of outcome measures. In evaluating response to therapy, we monitored whether individual subjects received additional therapy, how home caregivers described disease severity, and whether home caregivers sought additional medical evaluation. Each of these outcome measures is subjective and, therefore, may not accurately reflect true disease severity. The double-blind, randomized, placebo-controlled study design should have minimized this effect.

After enrolling patients for 12 months, it was discovered that, due to an error in the randomization process at 1 institution, too few patients were being assigned to the placebo group. The initial randomization ratio of 1:1:1 (oral-nebulized-placebo) was changed to 1:1:3 at both institutions and enrollment continued. The pharmacists performing the randomization and 4 of us (J.W.L., J.A.G., G.A.D., and R.M.R.) were notified of the randomization error. No one involved with data collection was informed to avoid any potential bias. There was no difference in the age, sex, symptom duration, or croup scores of patients enrolled during the first year of the study and those enrolled subsequently. Therefore, we believe the change in the randomization procedure did not affect the results of the study.

Our sample size calculation was not based on the primary outcome measure. At the time the study was initiated, however, we could not identify any published data estimating the percentage of untreated ED patients with mild croup who subsequently required treatment with corticosteroids. Based on available data, we planned to enroll 150 patients. After discovering the randomization error, it was necessary to enroll more patients than the original estimation to ensure near-equal numbers of subjects in each group. This is why the study group included more than 80 patients per group.

We observed a P value of .05 for our primary outcome measure, treatment failure. A post hoc power calculation revealed that the study had 58% power to detect the observed difference in treatment failures. In the

Table 3. Patient Characteristics at Study Enrollment*

Variable	Oral Treatment Group	Nebulized Treatment Group	Placebo Treatment Group	P Value†
Age, mean (range), mo	28 (6-70)	31 (6-71)	26 (6-71)	.16
Sex, No. (%) of males	61 (72)	58 (64)	57 (65)	.48
Race, No. (%) of white patients	55 (65)	74 (81)	64 (72)	.06
Symptom duration, mean, h	26	25	25	.69
Mean/median croup score (range)	1.6/1 (0-6)	1.6/1 (0-5)	1.7/1 (0-5)	.94
Patients with access to a humidifier, No. (%)	52 (66)	59 (68)	58 (69)	.91
Patients with a history of croup, No. (%)	22 (26)	21 (24)	11 (13)	.07
Caregivers with experience with croup, No. (%)	37 (45)	34 (40)	29 (35)	.45
Patients with a smoker in the home, No. (%)	41 (52)	37 (44)	33 (42)	.42

*Oral treatment group indicates those who received 0.6 mg/kg of oral dexamethasone and nebulized placebo (ie, a 1-mg/mL solution of Dexamethasone Intensol; Roxane Laboratories Inc, subsidiary of Boehringer Ingelheim Corp, Ridgefield, Conn); nebulized treatment group, those who received oral placebo and 160 µg of nebulized dexamethasone sodium phosphate; placebo treatment group, those who received oral and nebulized placebo.
† $P < .05$.

Table 4. Viral Isolates From Nasopharyngeal Cultures*

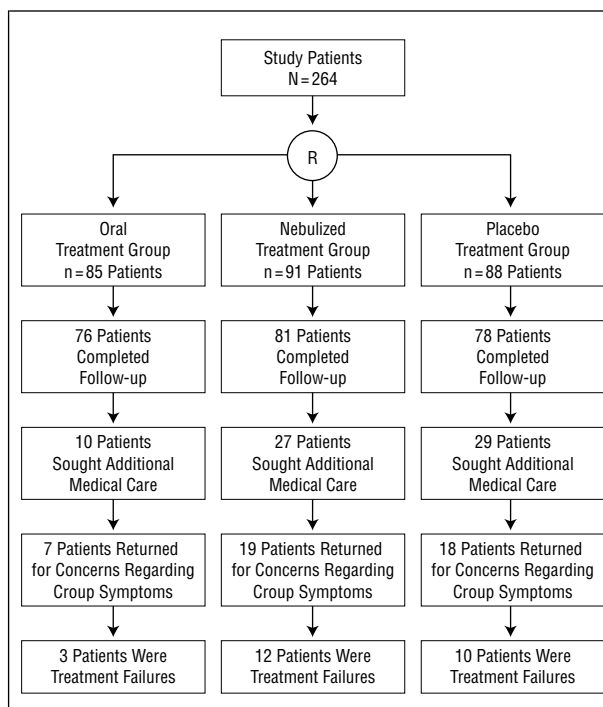
Culture Result	Oral Treatment Group	Nebulized Treatment Group	Placebo Treatment Group
No growth	44	48	46
Parainfluenza			
Type 1	21	21	30
Type 2	12	10	2
Type 3	1	0	1
Type 4	0	1	1
Influenza type A	2	6	1
RSV†	2	1	1
Other	0	1	1

*Oral treatment group indicates those who received 0.6 mg/kg of oral dexamethasone and nebulized placebo (ie, a 1-mg/mL solution of Dexamethasone Intensol; Roxane Laboratories Inc, subsidiary of Boehringer Ingelheim Corp, Ridgefield, Conn); nebulized treatment group, those who received oral placebo and 160 µg of nebulized dexamethasone sodium phosphate; placebo treatment group, those who received oral and nebulized placebo.
†RSV indicates respiratory syncytial virus.

context of the clinical data and number-needed-to-treat calculation, we believe the observed *P* value represents a type II error.

It is also important to consider the enrollment criteria of the study. Patients were eligible for the study if the responsible ED physician did not believe they required corticosteroids and/or racemic epinephrine. At the time of the project, this was a practical criterion because we were interested in knowing if patients with croup who were not receiving corticosteroids would benefit from their administration.

Some might argue that the administration of oral corticosteroids to every ED patient with croup constitutes an overly aggressive approach to this clinical process. A selective approach to corticosteroid administration would likely focus on patients who present without stridor. To our knowledge, there are no studies that specifically address the use of corticosteroids in this patient population. Fifty-four patients (21%) in this study presented without stridor. Three of these subjects sought additional care due to concerns regarding their croup symptoms. Two were in the placebo-treated group and 1 was in the nebulized dexamethasone-treated group. Unfor-



Study flowchart. R indicates randomization; oral treatment group, those who received 0.6 mg/kg of oral dexamethasone and nebulized placebo (ie, a 1-mg/mL solution of Dexamethasone Intensol; Roxane Laboratories Inc, a subsidiary of Boehringer Ingelheim Corp, Ridgefield, Conn); nebulized treatment group, those who received oral placebo and 160 µg of nebulized dexamethasone sodium phosphate; and placebo treatment group, those who received oral and nebulized placebo. For a description of how patients were randomized to 1 of the 3 study arms, see the "Patients and Methods" section.

unately, this is too little data to draw any meaningful conclusions about this subgroup of patients.

There are some facts that support prescribing oral dexamethasone to all patients with croup who present to the ED. In our study population of patients with mild disease, a clinician would have to treat only 10 patients with oral dexamethasone to prevent 1 child from coming back with clinically significant croup symptoms. In addition, this medication has an excellent safety profile and is inexpensive. The hospital cost of a 10-mg dose of dexamethasone (Dexamethasone Intensol) is approximately \$4. The oral administration of the parenteral form of dexamethasone is even less expensive. Since 1

What This Study Adds

While the effectiveness of dexamethasone as a treatment for patients with moderate to severe croup is well established, few studies have examined the use of this treatment for mild croup. Little data are related to the use of nebulized dexamethasone as a treatment for croup. This study addresses the need for additional information regarding the effectiveness of oral and inhaled dexamethasone for treating patients with mild disease. The results indicate that patients with mild croup treated with oral dexamethasone are less likely to seek subsequent care and demonstrate more rapid clinical improvement compared with those who receive nebulized dexamethasone or placebo.

dose is needed to complete treatment, compliance is not an issue.

Smaller doses of oral dexamethasone may also be effective. In a study of patients with moderate to severe croup, oral dexamethasone doses of 0.6 mg/kg, 0.3 mg/kg, and 0.15 mg/kg were shown to be equally effective for abating croup symptoms.¹³ Geelhoed¹⁴ also reported that the introduction of corticosteroid treatment at his hospital resulted in a decrease in the number of intubations, intensive care unit days, and length of stay for patients with croup. These effects have been maintained even as the routine dexamethasone dose has decreased from 0.6 mg/kg to 0.15 mg/kg.

The dose and method of drug provision for the nebulized dexamethasone-treated arm are also important limitations of this study. When we initiated the project, we identified no published reports examining the effectiveness of nebulized dexamethasone for treating croup. We selected 160 µg because it was equivalent to 2 puffs of a commercially available dexamethasone-metered-dose inhaler. We subsequently identified 1 study that examined the use of aerosolized dexamethasone for croup.¹⁰ In that report, children with moderately severe disease were given 10 to 20 mg of nebulized dexamethasone sodium phosphate or placebo. Dexamethasone-treated patients showed improvement in their croup scores at 4 hours compared with controls. There was no statistical difference between the 2 groups with regard to hospitalization rates and 2 patients in the treatment group developed bacterial tracheitis.

In our study, aerosolized dexamethasone was delivered via an updraft nebulizer. Consequently, much of the drug may have been lost through the ventilation holes in the mask. This may be especially true for children who are not used to receiving aerosols since they often cry or scream during the treatment. The small dose and use of an updraft nebulizer probably resulted in little actual drug delivery to the patients and may account for the similarity between the nebulized dexamethasone-treated and placebo-treated groups.

CONCLUSIONS

Children who present to the ED during the first 2 days of viral croup benefit from a single dose of oral dexamethasone. Further studies may help with specific dosing questions and whether inhaled dexamethasone is of any value.

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Corresponding author and reprints: Joseph Luria, MD, Division of Emergency Medicine, Children's Hospital Medical Center, 3333 Burnet Ave OSB-4, Cincinnati, OH 45229-3039 (e-mail: joe.luria@chmcc.org).

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