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Pediatrics 2000;106;1344-1348

DOI: 10.1542/peds.106.6.1344

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Outpatient Treatment of Moderate Croup With Dexamethasone: Intramuscular Versus Oral Dosing

Kristine K. Rittichier, MD*, and Carol A. Ledwith, MD†

ABSTRACT. *Objective.* Steroid use for the treatment of croup has been supported by several studies, although few have addressed the use of oral dexamethasone for outpatient management. The efficacy of oral (PO) versus intramuscular (IM) dosing of dexamethasone in the outpatient treatment of moderate croup are compared in this study.

Methods. Patients between the ages of 3 months and 12 years with moderate croup (history or presence of stridor, cyanosis, or retractions) were eligible for enrollment in this single-blind, prospective study. Patients were randomized to receive a single dose (0.6 mg/kg, maximum 8 mg) of IM or PO dexamethasone. Parents were contacted by phone to assess resolution of symptoms and need for further evaluation.

Results. Two hundred seventy-seven patients were enrolled (median age: 2.1 years). One hundred thirty-nine patients received IM dexamethasone, and 138 received PO. At phone follow-up, 141 (51%) had total resolution of symptoms (75 in IM, 66 in PO). Eighty patients (29%) returned for further evaluation (45 in IM, 35 in PO). Twenty-three (8%) received either more steroids, racemic epinephrine, or admission (11 in IM, 12 in PO).

Conclusion. No statistically significant difference was found in the need for subsequent interventions after a single dose of either IM or PO dexamethasone. A single PO dose of dexamethasone can be effectively and safely used for the outpatient treatment of moderate croup. *Pediatrics* 2000;106:1344–1348; croup, dexamethasone, laryngotracheobronchitis, pediatrics.

ABBREVIATIONS. IM, intramuscular; PO, oral; ED, emergency department; PCP, primary care provider.

Croup, or acute laryngotracheobronchitis, is the most common cause of upper airway obstruction in children. Croup produces subglottic edema to varying degrees and affects children between the ages of 6 months and 12 years,^{1,2} with a peak incidence of 2 years of age. The clinical syndrome consists of hoarseness and barking cough, with or without inspiratory stridor. Preceding symptoms often include congestion, runny nose, and fever. Se-

vere cases may present with cyanosis and respiratory distress.

Croup is caused by several viruses, of which the most common are parainfluenza type I and III, respiratory syncytial virus, and influenza.¹ The natural course of the illness includes peaking of symptoms between 24 and 48 hours after the onset of barking cough with expected resolution of all symptoms over a week.

Current emergency management for moderate to severe croup consists of cool mist therapy, steroids, and/or nebulized racemic epinephrine.^{2–4} The literature on croup has convincingly demonstrated benefit from steroid treatment with respect to improvement of croup scores, decreased need for further therapy, and decreased hospitalization rates.^{5–10} Two meta-analyses of steroid use in croup support their use for patients with moderate to severe croup.^{11,12} The studies cited in these manuscripts have used multiple routes of administration including parenteral, nebulized, and oral (PO) dosing. No study has directly compared intramuscular (IM) dexamethasone with PO dosing.^{3,13}

The objective of this study was to compare PO with IM dexamethasone in the outpatient treatment of patients with moderate croup. We hypothesized that each group would have similar numbers of patients requiring further treatments including racemic epinephrine, steroids, and hospitalization rates. The potential benefit to the study would include decreasing the use of IM injections for administering dexamethasone.

METHODS

Patients diagnosed with croup in the emergency department (ED) at the Children's Hospital in Denver, Colorado, were eligible for study enrollment. Patients were included if they were between the ages of 3 months and 12 years, had moderate croup, and had onset of illness for <48 hours. Moderate croup was defined as a clinical syndrome of hoarseness and barking cough associated with either a clear history of or presence of stridor at rest, and/or retractions. Onset of illness was defined as the onset of barking cough. Patients were enrolled during a 33-month period from October 1996 to June 1999.

Patients were excluded if they had epiglottitis, foreign body aspiration, reactive airway exacerbation, acute bacterial pneumonia, acquired or congenital upper airway anomalies such as tracheomalacia, or were immunocompromised. Patients were also excluded if they had a history of steroid exposure in the previous 2 weeks.

Patients with mild croup—defined as history or presence of barking cough only without the presence or history of associated stridor or retractions—were not eligible for inclusion. Likewise, patients with altered mental status, severe retractions, and/or cyanosis associated with their croup—severe croup—were ex-

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Presented at the National Society of Academic Emergency Medicine Conference; May 20–23, 1999; Boston, MA.

Received for publication Jan 14, 2000; accepted May 9, 2000.

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cluded. Any patient who was admitted to the hospital during the initial ED visit, either before consideration or after enrollment in the study, were also excluded from the study. The study clearly included only those patients with croup who had presence or history of stridor at rest and/or retractions.

Pediatric ED attending physicians, fellows, and residents enrolled patients in the study. Initial medical evaluation included a history and physical examination. All patients were given cool mist therapy per our ED protocol. Other treatments, including nebulized racemic epinephrine, antibiotics for concurrent infections, or admission, were administered at the discretion of the attending physician. Patients who responded to cool mist treatment alone were not excluded from the study.

Patients enrolled in the study were given either IM dexamethasone or PO dexamethasone using a random allocation chart based on a table of random numbers. The randomization code was held by the nursing staff in the ED. Both IM and PO dexamethasone were given as a single dose of 0.6 mg/kg (maximum: 8 mg). Nurses administered the dexamethasone either orally or intramuscularly per hospital protocol. PO dexamethasone was administered by means of a crushed tablet mixed with flavored syrup or jelly. Liquid dexamethasone was not used. To help with blinding of the physician, who then re-examined the patient, Band-Aids (Johnson & Johnson, New Brunswick, NJ) were placed on all patients whether they received PO or IM medicine. No additional steroids were given or prescribed at the time of discharge from the ED.

Demographic information, as well as information regarding signs, symptoms, and duration of the illness, were collected on all patients enrolled in the study. All subjects were assigned a pretreatment score based on the Westley score introduced in 1978 to measure pretreatment severity and confirm randomization of the 2 groups.¹⁴ Because we enrolled only those patients with moderate croup and excluded those with cyanosis and altered mental status, the range of croup scores were 0 to 5 for this study.

At discharge, patients were scored again with the Westley scale to assess improvement in the ED. Caretakers were provided with an information sheet on croup, home remedies, and a list of signs and symptoms of worsening status for which to return. The home instruction sheet is a standard form adapted with permission from *Your Child's Health* by Barton Schmitt, MD.¹⁵ There was no specific directive in the study protocol to have patients reevaluated after their initial ED visit.

Caretakers were contacted by phone 48 to 72 hours after the acute care visit by a caller who was blinded to the route of administration of the dexamethasone. Caretakers were instructed at the initial visit to not disclose the route of administration of the medicine to the caller. Information was collected about the need for further care and any treatment rendered after the initial visit. Caretakers were also asked about the patients' clinical status and were asked to rank their child's clinical status on this 4-point ordinal scale:

1. Symptoms worse than initial visit
2. Symptoms the same as the initial visit
3. Symptoms better than the initial visit, and
4. Resolution of all signs and symptoms.¹⁶

Unscheduled return visits are defined as patient visits for the same illness to a health care facility or a primary care provider's (PCP's) office after the initial ED visit. Unscheduled return failures are defined as subsequent visits that required additional croup treatment, either additional steroids, racemic epinephrine, and/or hospitalizations.

Data Analysis

The primary outcome measure in this study was the need for further therapy after the initial ED visit including a reevaluation at their PCP's office, additional steroids, additional racemic epinephrine treatments, or hospital admissions. The secondary outcome measure was the parental report of improvement at the follow-up phone call.

Based on an estimated need for further treatment in the IM group of 5%, it was deemed that 140 patients would be needed in each group to detect a 10% difference with an α of 0.05 and a power of 0.80. A difference of 10% was deemed to be a statistically significant difference between the 2 routes of administration.

For statistical analysis, data are expressed as numbers of pa-

TABLE 1. Demographics

	Total	IM	PO
<i>n</i>	277	139	138
Male	192 (69%)	97	95
Female	85 (31%)	42	43
Age (y)*	2.07 ± 1.82	2.03 ± 1.81	2.01 ± 1.84

* Median ± standard deviation.

tients unless otherwise stated. For continuous variables, differences between 2 administrations (IM versus PO) were tested using 2 sample Student's *t* tests. χ^2 and Fisher's Exact tests were used to compare dichotomous data between the 2 administrations. The Wilcoxon Rank-Sum test was used to compare score data between the 2 administrations. Logistic regression analysis was conducted to observe relations of binary outcomes of interests and other variables. Odds ratios, corresponding 95% confidence intervals, and *P* values are reported. Two-tailed values are considered significant at *P* < .05.

This study was approved and monitored by the Colorado Multiple Institutional Review Board. Written informed consent signed by the parent or guardian was required for enrollment. Assent from the child was obtained if the patient was 6 years or older.

RESULTS

Twelve hundred ninety-eight patients were diagnosed with croup at Children's Hospital during the study period. The majority of these patients were not considered for enrollment in the study because they failed to meet inclusion criteria. Of those who met the inclusion criteria, 317 patients were then initially enrolled in this study. Nine patients were excluded from the study as they were subsequently admitted to the hospital during their initial ED visit. Four patients were excluded after enrollment because they had a barky cough for >48 hours. Twenty-seven patients were unable to be contacted by phone and were excluded, including 10 patients whose enrollment forms were lost in the physical opening and move to the new ED in the hospital.

The remaining 277 patients met inclusion criteria for this study and were analyzed. One hundred thirty nine patients received IM dexamethasone and 138 received PO.

Gender and ages of patients are evenly distributed for each administration (Table 1). Table 2 contains variables of interest and shows no statistically significant differences between the 2 administrations except for fever.

At phone follow-up, 80 patients were evaluated for a second visit, the unscheduled return. The number of patients who received additional steroids, subsequent racemic epinephrine, and hospital admissions at this second visit accounted for 8% of the total 277

TABLE 2. Initial Visit Data

	Total	IM	PO	<i>P</i> Values
Illness <24 h	235 (85%)	116 (83%)	119 (86%)	.519
Fever	183 (66%)	82 (59%)	101 (73%)	.013
Admit score >2	89 (32%)	46 (33%)	43 (31%)	.730
Admit score = 2	57 (21%)	31 (22%)	26 (19%)	
Admit score = 1	88 (32%)	43 (32%)	45 (32%)	
Admit score (mean)		2.09	1.95	.392
Discharge score (mean)		0.42	0.38	.311
Racemic epinephrine	61 (22%)	32 (23%)	29 (21%)	.687

patients (Table 3). These were defined as the unscheduled return failures.

The relative risks between IM and PO dexamethasone for receiving additional steroids, racemic epinephrine, or hospital admission are listed in Table 3 along with the 95% confidence intervals. Table 4 itemized all treatments received by those patients who saw their PCP for a second visit ($n = 80$).

Our second outcome, caretaker report of patients' symptoms, was also evaluated at the follow-up phone call. Seventy-five patients in the IM and 66 patients in the PO group reported resolution of all symptoms (caretaker score: 3). Fifty-eight patients in the IM group and 65 patients in the PO group reported improvement in croup symptoms (caretaker score: 3). There was no statistical difference between the 2 treatment groups in consideration with this outcome with a P value of .31.

Using logistic regression analysis of factors, unscheduled returns had a statistically significant correlation with admit score and racemic epinephrine given at the initial visit (Table 5). There was a borderline significance for duration of illness, although it was not statistically significant. For each increment of the admit score, it was 1.309 times more likely for the patient to return for a second visit. It was 2.932 times more likely for a repeat visit if the patient had received a racemic epinephrine at the initial visit than for those who did not receive a racemic epinephrine treatment. It was 0.444 times less likely for a patient to return if they have been sick for 2 days rather than for 1 day.

Three additional subsets of patients were also analyzed with respect to the 2 outcomes. These subsets included those patients with illness lasting <24 hours, those who had received a racemic epinephrine at the initial ED evaluation, and those with a croup score >2 at initial visit. No statistical significance was found between the 2 administration routes of dexamethasone with regard to further treatment or parental report of symptoms. Of note, all patients who received additional racemic epinephrine treatments and hospital admission on subsequent visits were in the subset of patients with illness lasting <24 hours. The numbers were too small to analyze statistically.

DISCUSSION

Although historically rife with controversy, ample evidence now exists to support the use of steroids in the management of severe, moderate, and even mild croup. Before the widespread use of steroids, up to 15% of affected children required admission to the

TABLE 4. For Those Who Had Unscheduled Returns

	IM	PO
Treatments		
None	23	18
Mist	3	4
Antibiotics	7	1
Albuterol	3	0
OTC cough preparation	0	2
Steroids	11	12
Racemic epinephrine	2	3
Admission	2	2

TABLE 5. Logistic Regression Analysis Results

	Odds Ratio	95% Confidence Intervals	P Value
Unscheduled return versus admit score	1.309	(1.112,1.540)	.0012
Unscheduled return versus duration of illness	0.444	(0.188,1.046)	.0633
Unscheduled return versus racemic epinephrine	2.932	(1.621,5.303)	.0004

hospital.² That number has declined with the acceptance and beneficial use of steroids for croup.³ The admission rate during our study period was <1% (116/1298 patients), with the majority (92 patients) admitted to our overnight observation unit.

The literature on croup that supports the use of steroids is based mostly on hospitalized patients,^{5-8,17} and the majority use IM dosing.^{5-7,15,17-19} More recent studies have focused on outpatient management,^{16,20,21} and oral preparations, although not yet well-studied, are widely used clinically in both office practice and acute care settings.^{22,23} The PO route of administration has as effective an assumed serum concentration as the IM route, and its absorption and bioavailability are approximately 80%.²⁴ The most commonly used steroid in treating croup is dexamethasone sodium phosphate because of its antiinflammatory potency, its long biological half-life (36-54 hours), and duration of action.²⁵

The purpose of our study was to directly compare the use of PO versus IM dosing of dexamethasone in the outpatient treatment of moderate croup. No study to date in the literature addresses this comparison. Our primary outcome was the need for further treatments after discharge from the ED. Our secondary outcome was caregiver report of patient symptoms at 48 hours phone follow-up.

Our study was not designed to determine the beneficial effect of steroids on our study population. Although a persistent slight amount of skepticism still exists, we felt that previous studies supported

TABLE 3. Subsequent Visits

	Total	IM	PO	P Values	Relative Risk	95% Confidence Intervals
Unscheduled returns	80 (29%)	45 (32%)	35 (25%)	0.198	0.783	(0.539,1.138)
Steroids	23 (8%)	11 (8%)	12 (9%)	0.814	0.913	(0.586,1.423)
Racemic	5 (2%)	2 (1%)	3 (2%)	0.684	1.511	(0.256,8.903)
Admission	4 (1%)	2 (1%)	2 (1%)	1.000	1.007	(0.144,7.050)
Unscheduled return failure	23 (8%)	11 (8%)	12 (9%)	0.814	1.099	(0.502,2.405)

the beneficial use of steroids in moderate, and even mild, croup. We, therefore, directly compared the 2 treatment administration groups and did not compare the 2 with placebo.

In our study, 29% ($n = 80$) of patients returned for a second evaluation even though there was no direct instruction to return. The majority of these patients ($n = 57$) received only reassurance at the repeat visit. Only 8% ($n = 23$) of patients were deemed by the caregiver to require additional croup treatment. These unscheduled return failures were similar in both the PO and IM groups. Only 4 patients were hospitalized on the repeat visit (2 patients in each group).

The almost identical number of unscheduled return failures in each group supports the idea that PO dexamethasone works as well clinically as IM dexamethasone in the treatment of outpatient croup. The difference between the groups was also found to carry no statistical significance.

By administering PO dexamethasone instead of IM to croup patients, the pain and risks associated with injections can be avoided. Oral dexamethasone is easier to administer and more widely available for the office physician. Both PO and IM dexamethasone are fairly inexpensive, and no additional financial benefit would be obtained from using one or the other. However, PO administration potentially could save on additional charges incurred from administration of IM injections.

In our study, the relative risk of receiving additional steroids if given IM dexamethasone at enrollment was 0.91 as compared with PO. The relative risk for additional racemic epinephrine treatments and hospital admission centered around 1.0 to 1.5 with a wide range for the 95% confidence intervals. The numbers of patients who required these treatments was small and resulted in these wide confidence intervals. A much larger study of croup patients would have narrowed the confidence intervals.

The low number of unscheduled return failures shown in our study is also supported in other studies of outpatient croup management. Luria et al²⁰ compared PO dexamethasone, nebulized dexamethasone, and placebo in 255 outpatients with mild to moderate croup. The primary outcome in their study was treatment failures defined as receiving steroids during the subsequent 7 days after enrollment. They showed a 4% failure rate in the PO group, a 13% failure rate in the nebulized group, and a 11% failure rate in the placebo group.

Geelhoed et al²¹ in a study of 100 patients with mild croup had a 0% failure rate in those patient treated with 0.15 mg/kg of PO dexamethasone. The failure rate in those treated with placebo was 16%. Their study excluded all patients with moderate and severe croup. The difference in failure rates in these 2 studies compared with our 8% rate of unscheduled return failures appears to be related to our enrollment of more ill children as the above studies excluded patients who received racemic epinephrine treatments at the initial visit²⁰ and those who had moderate croup.²¹

There were a handful of patients in our study who

received additional treatments such as antibiotics, cough preparations, or nebulized albuterol at the second visit. Interestingly, 1 patient was diagnosed with a positive pertussis culture on this second visit.

Using logistic regression analysis on our 80 patients who returned for a second visit, we found an association between unscheduled returns with higher admit croup scores and racemic epinephrine treatments given at the initial ED visit. Patients were almost 1.3 times more likely to seek additional care if they had a higher croup score on initial visit, and 2.9 times more likely to seek care if they had received a racemic epinephrine treatment at the initial visit. It appears as if parents returned for a follow-up visit if their children appeared more ill on initial presentation, even when not directly told to follow-up. However, the majority of unscheduled returns received only reassurance on this repeat visit.

In an attempt to select a more ill population of patients from our total study population, we further analyzed 3 subsets of patients. Patients who were on their first day of illness, those with a croup score >2 at presentation, and those who had received a racemic epinephrine at enrollment comprised the 3 groups. No statistical difference was found between the IM and PO groups in these 3 subsets with respect to both primary and secondary outcomes. This suggests that even in the more severely affected patients, PO dexamethasone works as well as IM in the treatment of outpatient croup.

Also of interest, all of the patients who received additional racemic epinephrine treatments and hospitalization on the second visit were in the subset of patients who, at enrollment, had illness <24 hours. Because most of the return visits were on the day following the initial ED visit, the lack of clinical improvement may be related to the natural course of the illness with expected worsening on the second day or night. Although this study did not address the issue of multiple doses of PO dexamethasone in croup patients, the implication exists that those patients who are on their first day of illness might benefit from additional doses of steroids.

The inability to tolerate PO dexamethasone has been used to argue for the use of IM dosing. Madhok et al²⁶ when comparing PO dexamethasone and nebulized dexamethasone showed a preference by both parents and nurses/respiratory therapist for nebulized dexamethasone secondary to an increased incidence of vomiting with the PO preparation. In our study, only 1 patient vomited the initial dose of PO dexamethasone and later tolerated a repeat dose of PO medicine. Our nurses prepare the PO dose by crushing dexamethasone tablets and mixing the pill fragments with flavored syrup. In our experience, this preparation has been better tolerated in our ED patients than the commercially prepared liquid solution of dexamethasone.

Placebo controls were not used in our study as this was felt to denote deviation from the standard of care for croup in our ED and our community. Using a placebo, in our opinion, was withholding treatment that had been shown to be beneficial for patients, and giving placebo to a subpopulation of patients placed

them at too great a risk of relapse and need for further treatment.

CONCLUSION

Dexamethasone given orally to outpatients with moderate croup is well-tolerated and is as effective as IM administration. After a single dose of dexamethasone, both IM and PO groups had similar rates of unscheduled returns and the need for additional croup treatments. This comparison provides support for the use of PO dosing of dexamethasone in acute care settings, EDs, and office practice. PO dosing is inexpensive, readily available, and easily administered. PO administration also obviates the need for a painful and unnecessary IM injection, unless the PO preparation is not tolerated. Dexamethasone that is administered PO potentially decreases anxiety and complications inherent in IM injections, thus improving patient tolerance and parent satisfaction with the visit.

ACKNOWLEDGMENTS

We thank Amy Cotter, RN, for collection of data and Misou Ellison, MS, for statistical help.

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The Guardian. April 26, 2000

Noted by JFL, MD

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