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Original Article

Efficacy of Oral Dexamethasone versus Parenteral Dexamethasone in the Management of Mild to Moderate Croup

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ABSTRACT

Croup is a common cause of upper airway obstruction in children, characterized by a barking cough, stridor, and respiratory distress. While corticosteroids, particularly dexamethasone, are the cornerstone of treatment, the optimal, least invasive route remains debated, especially for mild-to-moderate cases. **Objectives:** To compare the efficacy of oral versus parenteral dexamethasone in children presenting with mild to moderate croup. **Methods:** This randomized controlled trial was conducted at the Department of Pediatrics, Khyber Teaching Hospital, Peshawar, from Oct 2024 to Mar 2025. A total of 200 children aged 6 months to 6 years with mild to moderate croup were randomized into two equal groups to receive a single dose of dexamethasone either orally (Group PO) or intramuscularly (Group IM) at 0.15 mg/kg. The primary outcome was improvement in the Westley Croup Score at 4, 8, and 24 hours. Secondary outcomes included respiratory rate, stridor, need for additional interventions, and parental satisfaction. Outcomes were compared between the groups using appropriate statistical tests, with a p-value of <0.05 considered significant. **Results:** The mean age was 23.5 ± 12.4 months. The Westley Croup Score and respiratory rate were significantly higher in Group PO at 4 hours (p=0.03), but comparable at 8 and 24 hours. No significant differences were noted regarding stridor or requirement for additional interventions. Parental satisfaction was significantly higher in Group PO (p=0.01). **Conclusions:** Oral dexamethasone is as effective and well-tolerated as intramuscular administration for mild to moderate croup in children under six years, with higher parental satisfaction.

INTRODUCTION

Croup is a common cause of acute upper airway obstruction in children and accounts for a substantial proportion of pediatric respiratory emergency presentations. The condition is commonly reported among children under 6 years of age, with the peak incidence occurring during the second year of life [1]. The upper airways are in an inflammatory state during an episode of croup. This leads to the characteristic symptoms of a barking cough, hoarseness, and inspiratory stridor, often accompanied by varying degrees of respiratory distress. There may be mild, moderate, or severe symptoms in croup, which typically worsen at night [2]. The pathophysiology of the disease involves inflammation and subsequent narrowing of the subglottic region. Croup typically results from viral infections, with parainfluenza virus types 1 and 3 being the predominant etiological agents, though other pathogens may also contribute to the disease burden [3, 4]. Several differential diagnoses should be considered while evaluating a child with the symptoms of croup. The most important among these are bacterial tracheitis, epiglottitis, and foreign body aspiration [5, 6]. Various clinical scoring systems are used to assess the severity of croup; however, the Westley Croup (WC) score is the most commonly accepted scale. This system

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categorizes croup into mild, moderate, and severe cases. The mild cases typically involve a barking cough with no stridor at rest, whereas moderate croup also includes stridor at rest and signs of respiratory distress, such as intercostal retractions. Severe cases of croup, although not common, can progress to respiratory failure if not promptly treated [7]. At least 60% of children presenting to the emergency room have minor symptoms and are managed on an outpatient basis. The majority of these children with mild croup only have temporary symptoms, and just 15% of them require further medical evaluation. In the emergency treatment of croup, cool mist, nebulized racemic epinephrine, and corticosteroids (CS) are commonly employed [8]. The potent anti-inflammatory effects of CS help to reduce the laryngeal mucosal edema and improve clinical outcomes in the management of croup. With these proven benefits, CS is now established as the cornerstone therapy in the management of croup in pediatrics [9, 10]. Due to its high glucocorticoid potency, minimal mineralocorticoid activity, and long half-life of 36-72 hours, dexamethasone has emerged as the standard CS for croup. With these properties, dexamethasone provides sustained symptom relief through a single dose administration. Dexamethasone has traditionally been administered intramuscularly (IM) at a dosage of 0.6 mg/kg; however, recent studies have explored oral administration (PO) at doses of 0.15-0.6 mg/kg to minimize invasiveness while maintaining clinical efficacy. This PO administration has been shown to reduce airway inflammation, decrease hospitalization rates, improve symptoms, and shorten the duration of illness. The IM administration has been favored due to concerns about vomiting and uncertainty regarding bioavailability with oral administration [11]. On the other hand, the oral route offers a less invasive approach. This avoids unnecessary pain and distress in already anxious patients, which could otherwise complicate the clinical assessment and management for the care providers. Moreover, recent data suggested that oral administration may be equally effective, more acceptable to children and parents, and potentially more cost-effective in resource-limited settings [12]. By determining the efficacy of PO dexamethasone, the researchers can establish an evidence-based standard of care in current local health-care centers that may optimize treatment outcomes while minimizing iatrogenic distress faced by this vulnerable patient population.

Despite this established efficacy of dexamethasone, a debate persists regarding the optimal route of administration in children with croup, particularly for mild to moderate cases, which constitute the majority of presentations. This study was therefore designed to directly compare the efficacy of PO dexamethasone versus IM dexamethasone in managing mild to moderate croup. This comparison will provide valuable insight to choose the most appropriate and patient-friendly route of administration for effective croup management in available hospital settings.

METHODS

This randomized controlled trial was conducted at the Department of Pediatrics, Khyber Teaching Hospital, Peshawar, from Oct 2024 to Mar 2025 over a period of 6 months, with prior approval from the ethical committee of the hospital (IREB No. 410/DME/KMC, date: 23 May 2024). The trial was registered at ClinicalTrials.gov ID: NCT06959407. The sample size was calculated using the formula for comparison of two independent means: $n = 2(Z_a+Z_{1-\beta})^2\sigma^2 / \Delta^2$. where Z_α corresponds to the level of significance, $Z_{1-\beta}$ represents the study power, σ^2 denotes the pooled variance, and Δ represents the expected mean difference between the two groups. The sample size was estimated using Open Epi software based on values obtained from a referenced study, with an alpha of 5% (two-sided) and a study power of 90%. The mean respiratory rate at 1 hour following IM administration of dexamethasone was 41.66, while the mean respiratory rate at 1 hour following PO administration of dexamethasone was 45.53 [13]. The estimated sample size n1=65 and n2=65. Although the calculated sample size was 130, a total of 200 patients were included, with 100 patients in each group. This provided adequate statistical power to detect clinically meaningful differences. Children aged ≥6 months to < 6 years, presenting at the pediatric emergency and diagnosed with croup (presence of barking sounds with or without inspiratory stridor, having symptoms duration of <72 hours, and with Westley Croup score of ≤5) were enrolled through consecutive sampling. Exclusion criteria were set as patients with chronic pulmonary conditions (such as tuberculosis, bronchopulmonary dysplasia, or cystic fibrosis), known congenital or acquired airway anomalies, an immunocompromised state, or any known hypersensitivity to CS. Additionally, patients with prior use of systemic or inhaled CS or epinephrine within the past 14 to 28 days, and presentation with severe respiratory distress (Westley Croup Score >5) depending on the medication and route of prior corticosteroid exposure were excluded. Patients with a suspicion of bacterial tracheitis, epiglottitis, foreign body aspiration, or those who were unable to tolerate PO medications due to persistent vomiting or markedly reduced consciousness were also excluded. These exclusion criteria minimized the confounding factors such as prior steroid use and severe disease that could alter treatment response. Written consent was taken from the parents/guardians of enrolled children after explaining to them the purpose, risks, and

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benefits of the study. All the demographic data and related medical history were taken, including the patient's age, gender, weight, height, and duration of the symptoms of croup. Patients were then randomly allocated to "Group PO" and "Group IM" using block randomization (1:1 ratio), where Group IM served as the control group, as intramuscular dexamethasone is the standard treatment. While selection was non-probability-based, allocation was randomized. Children in Group PO received 0.15 mg/kg of dexamethasone orally as a single dose (which is consistent with current pediatric guidelines supporting lower effective doses for mild to moderate croup) while patients in Group IM received 0.15 mg/kg of dexamethasone intramuscularly [14]. The primary outcome of the study was set as improvement in WC score at 4-, 8-, and 24-hours post-treatment (a validated and widely used tool which is sensitive for assessing clinical severity and treatment response in croup)[15]. These time points were selected to cover both the early and sustained treatment response, as the onset of action of dexamethasone has been reported within 4 hours, with effects persisting up to 24 hours. Outcome assessors were not blinded to treatment allocation because the route of dexamethasone administration was apparent during clinical assessment. Clinically relevant secondary outcomes were selected to appropriately measure treatment response and to reflect patient-centered outcomes, including respiratory rate and presence of stridor at rest at 4- and 8-hours post-treatment. Any requirement for additional medical intervention, such as nebulized epinephrine, was also recorded.Parental satisfaction was assessed using a 5-point Likert-type scale (1 = very dissatisfied to 5 = very satisfied). The scale was not formally validated locally, and Cronbach's alpha was assessed post-hoc. The scale demonstrated acceptable internal consistency in previous studies, with a reported Cronbach's alpha value of ≥0.80, indicating good reliability. Test-retest reliability has also been shown to be satisfactory (ICC >0.75) in similar clinical settings [16]. The scale ranges from 1 to 5, where 1 = very dissatisfied, 2 = dissatisfied, 3 = neutral, 4 = satisfied, and 5 = very satisfied. The minimum possible score is 1, and the maximum is 5, with higher scores indicating greater patient/parent satisfaction with treatment and perceived effectiveness. These outcomes were selected for their clinical relevance and ability to provide a comprehensive assessment of both physiological response and patient-centered treatment effectiveness. The CONSORT Flow Diagram was shown (Figure 1).

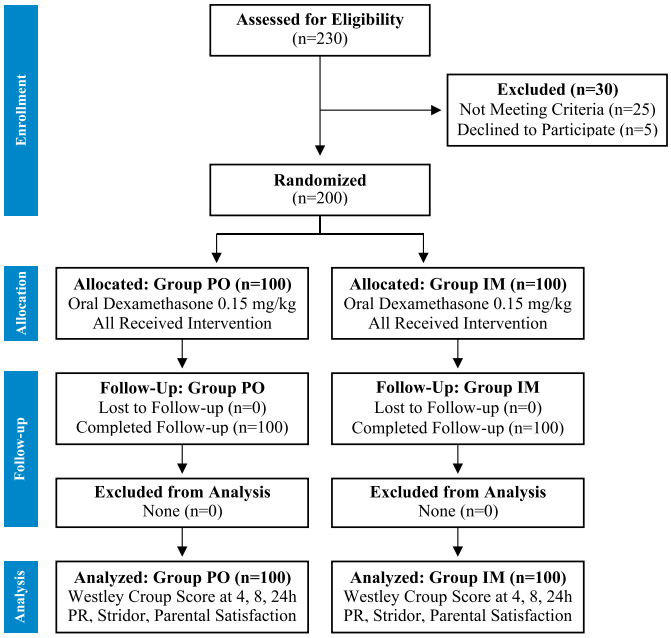


Figure 1: CONSORT Flow Diagram

Data analysis was performed using SPSS version 26.0. Continuous variables were expressed as mean ± standard deviation (SD) (after assessing the normality of data using the Shapiro–Wilk test), while categorical variables were shared as frequencies and percentages. Repeated measures ANOVA was used to assess within-group changes over time and the time × treatment-group interaction. Effect sizes were expressed as between-group mean differences (PO – IM) with 95% confidence intervals and standardized mean differences (Cohen's d with 95% confidence intervals) at each time point. An independent t-test was applied to compare continuous secondary outcomes between groups. Categorical variables were analyzed using the Chi-square test. A p-value of <0.05 was considered statistically significant.

RESULTS

The mean age of children in this study was 23.49 ± 12.35 months, ranging from 6 to 61 months. The baseline characteristics (age, gender, weight, height, duration of symptoms, and initial Westley score) showed no statistically significant differences between groups (all p > 0.05). This confirms that randomization achieved comparable baseline characteristics (Table 1).

Table 1: Demographic Variables and Clinical Parameters (n=200)

Demographic and Baseline Clinical Parameters	Group PO (n=100), Mean ± SD / n (%)	Group IM (n=100), Mean ± SD / n (%)	p-value
Age (Months)	23.9 ± 12.00	23.08 ± 12.73	0.64
Male	56 (56%)	51 (51%)	0.48
Female	44 (44%)	49 (49%)	
Weight (Kg)	12.28 ± 1.58	12.58 ± 1.57	0.18
Height (cm)	85.73 ± 3.11	86.15 ± 2.97	0.33

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Duration of Symptoms (Hours)	21.59 ± 7.93	22.45 ± 8.14	0.45
Westley Croup Score	3.51 ± 0.98	3.45 ± 0.99	0.67

Comparison of the primary outcomes showed that the WC score at 4 hours post-administration was significantly higher in Group PO compared with Group IM (p=0.03). However, no statistically significant differences were recorded at 8 and 24 hours (p=0.65 and p=0.80, respectively). Repeated measures ANOVA demonstrated a statistically significant reduction in WC Score over time within both groups (p<0.01), with no significant time-group interaction. The magnitude of the between-group difference at each time point is therefore given as effect sizes: mean differences (PO – IM) were 0.22 (95% CI 0.02 to 0.42), –0.01 (95% CI –0.05 to 0.03) and –0.02 (95% CI –0.18 to 0.14) at 4, 8 and 24 hours, respectively, corresponding to Cohen's d of 0.31 (95% CI 0.04 to 0.59), –0.06 (95% CI –0.34 to 0.21) and –0.04 (95% CI –0.31 to 0.24). These estimates indicate a small early difference at 4 hours that was not sustained at 8 and 24 hours (Table 2).

Table 2: Comparison of WC Score among the Groups (n=200)

Westley Croup Score at Different Follow-Up Times	Group PO (n=100), Mean ± SD	Group IM (n=100), Mean ± SD	p-value
At 4 Hours	2.84 ± 0.72	2.62 ± 0.68	0.03*
At 8 Hours	2.02 ± 0.14	2.03 ± 0.17	0.65
At 24 Hours	1.25 ± 0.56	1.27 ± 0.57	0.80

Indicates statistically significant difference (p ≤ 0.05*). Within-group comparisons were analyzed over time using repeated measures ANOVA (p < 0.001 for both groups†); the time-group interaction was not significant. Between-group mean differences (PO – IM) with 95% CI: 0.22 (0.02 to 0.42) at 4 h, –0.01 (–0.05 to 0.03) at 8 h and –0.02 (–0.18 to 0.14) at 24 h; Cohen's d with 95% CI: 0.31 (0.04 to 0.59), –0.06 (–0.34 to 0.21) and –0.04 (–0.31 to 0.24), respectively

Comparison of secondary outcomes showed a significantly higher respiratory rate at 4 hours in Group PO compared with Group IM (p=0.03), while this difference became non-significant at 8 hours (p = 0.13). No significant differences were observed between the groups in the presence of stridor at 4 or 8 hours (p=0.48 and p=0.70, respectively), or in need for additional interventions (p=0.52). Parental satisfaction scores were statistically higher in the PO group than in the IM group (4.63 ± 0.49 vs. 4.44 ± 0.57; p=0.01), although the between-group difference was small (0.19 points on a 5-point scale) (Table 3).

Table 3: Secondary Outcomes and Parental Satisfaction (n=200)

Secondary Outcomes and Parental Satisfaction	Group PO (n=100), Mean ± SD / n (%)	Group IM (n=100), Mean ± SD / n (%)	p-value
Respiratory Rate at 4 Hours	32.25 ± 1.97	31.66 ± 1.75	0.03*
Respiratory Rate At 8 Hours	29.51 ± 3.78	28.71 ± 3.69	0.13
Patients with Stridors at Rest at 4 Hours	12 (12)	9 (9)	0.48
Patients with Stridor at Rest At 8 Hours	4 (4)	3 (3)	0.70
Need For Nebulized Epinephrine	6 (6)	4 (4)	0.52
Parental Satisfaction Score at Likert Scale	4.63 ± 0.49	4.44 ± 0.57	0.01*

Indicates statistically significant difference (p ≤ 0.05*)

DISCUSSION

The mean age of children in the current study was 23.5 ± 12.4 months. Comparison of the primary outcomes showed that the WC score at 4 hours post-administration was statistically higher in Group PO than in Group IM (p=0.03), although the mean difference of 0.22 points is small and its clinical importance is uncertain. However, no statistically significant differences were recorded at 8 and 24 hours (p=0.65 and p=0.80, respectively). Comparison of secondary outcomes showed a significantly higher respiratory rate at 4 hours in Group PO compared with Group IM (p=0.03), while this difference became non-significant at 8 hours (p=0.13). No significant differences were observed between the groups in the presence of stridor at 4 or 8 hours (p=0.48 and p=0.70, respectively), or the need for additional interventions (p=0.52). Parental satisfaction scores were, however, significantly higher in Group PO compared with Group IM (p=0.01), reflecting greater acceptance of the non-invasive route in our local healthcare and social environment. Overall, both treatment routes demonstrated similar clinical efficacy beyond the early hours, with a preference for the oral dexamethasone administration route due to ease and greater acceptability. The comparison of different dexamethasone administration routes in pediatric patients with croup has been discussed in various studies and meta-analyses, aiming to find the method offering the most acceptable results to the patients and the healthcare providers. These findings of our study are aligned with several previous investigations. Soleimani *et al.* compared PO and IM dexamethasone in treating croup among 86 children aged 6 months to 6 years. Respiratory rate was significantly lower in the IM group in the initial hours (p=0.02), but no significant differences were observed afterward in respiratory rate, heart rate, O_2 saturation, or overall, WC scores. One patient from each group required hospital admission. Both routes were equally effective, with oral administration favored for being non-invasive [13]. Cabal *et al.* evaluated the results of three randomized studies to find whether IM steroids improve outcomes faster than oral steroids in children with croup. Their analysis found comparable outcomes between both routes, with no meaningful differences observed in clinical improvement, symptom resolution timeframes, Emergency Department returns, or requirements for additional therapeutic interventions. The mean WC scores were lower in the IM group (p=0.03) during initial hours, but no significant difference was observed thereafter [17]. A recently

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published cohort study by D'Arienzo *et al.* evaluated children hospitalized for croup receiving dexamethasone either IM or PO. In these 471 children, no significant difference was observed in the major outcomes. These outcomes included 30-day emergency department return rates, whether single or multiple doses of dexamethasone were given orally or intramuscularly. However, administration of more than a single dose was associated with a longer hospital stay, favoring the use of a single dose regardless of the route of administration [18]. In the randomized clinical trial by Dobrovoljac *et al.* an oral dose of 0.15 mg/kg dexamethasone significantly improved croup scores within 30 minutes, much earlier than the previously expected 4–6 hours [19]. Similarly, a pharmacokinetic study by Toledo *et al.* confirmed good bioavailability with oral administration, despite some differences among different oral concentrate formulations [20]. A systematic review of 10 studies by Mora *et al.* highlighted that CS, particularly dexamethasone, is highly effective in managing croup symptoms. The analysis found no significant differences between PO and IM administration routes, confirming their comparable efficacy. CS were found as the cornerstone of croup management across all clinical settings, outperforming other supportive treatments [17].

The present study has several limitations. First, Although the calculated sample size was 130, 200 participants were enrolled to increase the robustness of the findings and allow for potential loss to follow-up; however, the rationale for this increase was not prospectively documented. Second, the study used a lower dose of dexamethasone (0.15 mg/kg), which has demonstrated efficacy in mild-to-moderate croup; however, the findings may not be generalizable to higher-dose regimens, and further comparative studies are warranted. Third, outcome assessors were not blinded to treatment allocation, which may have introduced detection bias, particularly for subjective components of the Westley Croup Score and parental satisfaction. Fourth, the parental satisfaction scale was not formally validated in the local study population before the study, and its internal consistency was assessed post-hoc; consequently, the statistical difference in satisfaction should be interpreted cautiously. Fifth, the exclusion criterion regarding previous corticosteroid or epinephrine exposure should be interpreted according to the prespecified study protocol, and future studies should use a clearly defined uniform exclusion interval. Finally, although statistically significant differences in Westley Croup Score and respiratory rate were observed at 4 hours, the absolute differences were small and were not sustained at later time points. Longer follow-up and adequately powered trials using standardized, validated patient-reported outcome measures and blinded outcome assessment are warranted to determine whether any early difference between administration routes has meaningful clinical implications.

CONCLUSIONS

In children with mild to moderate croup treated with a single 0.15 mg/kg dose of dexamethasone, oral and intramuscular administration produced broadly similar clinical outcomes over 24 hours. Intramuscular dexamethasone was associated with statistically lower Westley Croup Scores and respiratory rates at 4 hours; however, the absolute differences were small and were not sustained at 8 or 24 hours. Oral dexamethasone was associated with a statistically higher parental satisfaction score, although the clinical importance of this difference is uncertain because the satisfaction measure was not formally validated in the study population. Overall, oral administration may represent a less invasive alternative to intramuscular administration for mild to moderate croup when oral medication can be tolerated, while the possibility of slightly faster early improvement with intramuscular administration should be acknowledged.

Authors' Contribution

Conceptualization: SK
Methodology: SA, AK
Formal analysis: SA, WA
Writing and Drafting: SK, IU, SS
Review and Editing: SA, SK, AK, IU, WA, SS

All authors approved the final manuscript and take responsibility for the integrity of the work

Conflict of Interest

All the authors declare no conflict of interest.

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