

# Oral dexamethasone led to fewer treatment failures than did nebulized dexamethasone or placebo in children with mild croup

Luria JW, Gonzalez-del-Rey JA, DiGiulio GA, et al. Effectiveness of oral or nebulized dexamethasone for children with mild croup. *Arch Pediatr Adolesc Med.* 2001 Dec;155:1340-5.

## QUESTION

In children with mild croup, does oral dexamethasone decrease the need for subsequent treatments and care and shorten symptom duration more than nebulized dexamethasone or placebo?

## DESIGN

Randomized (allocation concealed\*), blinded {patients, clinicians, outcome assessors, and data collectors}†, \* placebo-controlled trial with 7-day follow-up.

## SETTING

Emergency departments at 2 large urban tertiary care centers in Ohio, USA.

## PATIENTS

264 children between 6 months and 6 years of age (mean age 28 mo, 68% boys) who had symptoms of croup for < 48 hours. Exclusion criteria were severe disease, receipt of racemic epinephrine or corticosteroid treatment, spasmodic croup, or a history of prolonged endotracheal intubation or chronic respiratory illness. 84% of patients were assessed at day 7.

## INTERVENTION

Children were allocated to oral dexamethasone, 0.6 mg/kg of body weight to a maximum dose of 10 mg, and nebulized placebo ( $n = 85$ ); nebulized dexamethasone sodium phosphate, 160  $\mu\text{g}$  ( $n = 91$ ), and oral placebo; or oral and nebulized placebo ( $n = 88$ ).

## MAIN OUTCOME MEASURES

The primary outcome was treatment failure (re-evaluation leading to a prescription for corticosteroids or racemic epinephrine). Secondary outcomes were need for additional medical care and parental assessment of the child's condition.

## MAIN RESULTS

Analysis was by intention to treat. Fewer children in the oral-treatment group had treatment failure than did those in the nebulized-treatment or placebo groups (Table). Treatment failure did not differ between the nebulized-treatment and placebo groups (Table). Fewer children in the oral-treatment group needed additional medical care than did those in the nebulized-treatment and placebo groups (13% vs 33% vs 37%, respectively,  $P = 0.002$ ). Parents of children in the oral-treatment group reported greater im-

provement in their child's condition at day 1 than did parents of children in the nebulized and placebo groups ( $P < 0.001$ ). These results were not statistically different at days 2, 3, 4, or 7.

## CONCLUSION

In children with mild croup, oral dexamethasone led to fewer treatment failures, less need for additional medical care, and greater improvement in symptoms at 1 day than did nebulized dexamethasone or placebo.

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For correspondence: Dr. J. Luria, Children's Hospital Medical Center, Cincinnati, Ohio, USA. E-mail [joe.luria@chmcc.org](mailto:joe.luria@chmcc.org). ■

\*See Glossary.

†Information provided by author.

## Treatment failure of oral dexamethasone (OD) vs nebulized dexamethasone (ND) or placebo in children with mild croup at 7 days‡

OD	ND	Placebo	RRR (95% CI)	NNT (CI)
4%	—	14%	71% (6 to 91)	11 (5 to 155)
4%	16%	—	74% (17 to 92)	9 (5 to 49)
			RRR (CI)	NNH
—	16%	14%	11% (-48 to 137)	Not significant

‡Abbreviations defined in Glossary; RRR, RRI, NNT, NNH, and CI calculated from data in article.

## COMMENTARY

Establishing croup as a steroid-responsive disease has been one of the major advances in pediatric respiratory medicine in the past 10 years. Both oral dexamethasone and nebulized budesonide are effective, relieving symptoms of croup as early as 6 hours after treatment (1). With the battle won, what remains are largely minor skirmishes, such as those addressed in the study by Luria and colleagues. In this 3-way, randomized, placebo-controlled trial, dexamethasone given orally is compared with nebulized dexamethasone in mild croup. The results reconfirm that oral dexamethasone (0.6 mg/kg) is effective with a number needed to treat of 11, similar to that previously reported in a meta-analysis (1). Interestingly, and unlike the meta-analysis, nebulized steroid was no better than placebo. This finding probably occurred because (as Luria and colleagues discuss) the nebulized dose was far too low (160  $\mu\text{g}$ , which is equivalent to 2 puffs from a dexamethasone metered-dose inhaler).

Two points are worth noting. First, the oral dose used (0.6 mg/kg) is higher than necessary for effective treatment of mild croup (2). Second,

Luria and colleagues include no data on parent preference, nor do they include any analysis of cost benefit. In fact, as the authors comment, oral treatment is probably substantially cheaper and more convenient.

Some interesting questions remain. Dexamethasone is a particularly potent steroid. Are less potent steroids, like prednisolone, which is commonly used in asthma, as effective as dexamethasone? In more severe croup, is a combination of oral and nebulized drugs more effective? In the meantime, the message is clear: Oral dexamethasone remains the knockout winner for the treatment of croup.

James Y. Paton  
Royal Hospital for Sick Children  
Glasgow, Scotland, UK

## References

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