

# Inhaled budesonide and prednisone led to similar rates of asthma relapse after emergency department discharge

FitzGerald JM, Shragge D, Haddon J, et al. A randomized, controlled trial of high dose, inhaled budesonide versus oral prednisone in patients discharged from the emergency department following an acute asthma exacerbation. *Can Respir J*. 2000 Jan/Feb;7:61-7.

## QUESTION

In patients who are discharged from the emergency department after a severe acute asthma attack, do high doses of prednisone and inhaled budesonide lead to similar rates of asthma relapse?

## DESIGN

Randomized (unclear allocation concealment\*), blinded {clinicians, patients, outcome assessors, and statisticians}†, \* controlled trial with 7- to 10-day follow-up.

## SETTING

3 university-affiliated urban emergency departments in Canada.

## PATIENTS

185 patients who were 15 to 70 years of age, had an acute asthma exacerbation, were well enough to be discharged (postbronchodilator FEV<sub>1</sub> > 50% of predicted normal rate), and were able to use Turbuhaler correctly. Exclusion criteria included chronic obstructive pulmonary disease, intolerance to systemic glucocorticosteroids, peptic ulcer disease, active tuberculosis, fungal infection, type 1 diabetes mellitus, moderate-to-severe hypertension, pregnancy, lactation, or no effective contraception use (for women of

childbearing age). 82% of the patients completed the study, and 95% of the patients (mean age 28 y, 57% women) were included in the analysis.

## INTERVENTION

All patients received 1 dose of systemic glucocorticosteroids (intravenous methylprednisolone, 125 mg, or oral prednisone, 40 to 60 mg) before randomization. Patients were allocated to inhaled budesonide, 2400 µg/d given in 3 inhalations of 200 µg 4 times per day (*n* = 90), or to prednisone, 40 mg/d given once in the morning (*n* = 85) for 7 to 10 days.

## MAIN OUTCOME MEASURES

Relapse rate (return to the emergency department). Secondary outcome measures included adverse events and changes from baseline in FEV<sub>1</sub>, peak expiratory flow, self-rated symptom scores, and Asthma Quality of Life scores.

## MAIN RESULTS

Treatment groups had similar relapse rates (Table). The study had 80% power to detect a difference ≥ 10% at the 5% level of statistical significance. No differences in secondary outcomes existed between groups.

## CONCLUSION

In patients discharged from the emergency department after treatment with systemic corticosteroids for severe acute exacerbation of asthma, home use of inhaled budesonide and oral prednisone led to similar rates of relapse.

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\*See Glossary.

†Information provided by author.

## Inhaled budesonide vs prednisone in patients discharged from the emergency department after a severe acute exacerbation of asthma†

Outcomes at 7 to 10 d	Budesonide	Prednisone	RRR (95% CI)	NNT (CI)
Relapse rate	10%	12%	15% (-94 to 63)	Not significant

†Abbreviations defined in Glossary; RRR, NNT, and CI calculated from data in article.

## COMMENTARY

A particular strength of the study by FitzGerald and colleagues is that it had sufficient power to assess whether the 2 interventions led to equivalent relapse rates after discharge. Predefined equivalence limits were established, and sufficient numbers of patients were randomized to test the null hypothesis and show whether a difference in relapse rate existed between groups. 2 factors limit the generalizability of the findings. First, patients who had received a course of oral prednisolone in the month before enrollment were excluded. The influence of such patients who may have had more brittle disease or who may have been at higher risk for relapse cannot be predicted. Therefore, high-dose inhaled budesonide cannot be recommended in patients who present with a second exacerbation within a short (1-month) time period. Second, only 35% of patients were receiving any regular inhaled steroid at enrollment. It is not possible to determine whether patients who have never received inhaled steroids and patients who regularly receive such

treatment respond differently in terms of their likelihood of relapse. A subgroup analysis based on previous inhaled-steroid use would be inappropriate because the study does not have sufficient power to assess this.

This study provides encouraging evidence that a substantial proportion of adult patients attending the emergency department because of asthma exacerbations can be safely discharged home with a 7- to 10-day course of high-dose inhaled budesonide instead of a 7- to 10-day course of oral prednisone. However, further studies are required to investigate whether recent or maintenance inhaled-steroid use, or both, are important factors in determining response before high-dose budesonide can be recommended for all patients discharged from the emergency department after an acute asthma exacerbation.

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