Inhaled corticosteroids were safely stepped down in chronic, stable asthma

Hawkins G, McMahon AD, Twaddle S, *et al.* Stepping down inhaled corticosteroids in asthma: randomised controlled trial. *BMJ* 2003;**326**:1115–20.

Clinical impact ratings GP/FP/Primary care ★★★★★☆☆ Internal medicine ★★★★★☆☆
Respirology ★★★★★☆☆

Q In patients with chronic, stable asthma, can the dosage of inhaled corticosteroids be safely stepped down?

METHODS

Design: randomised controlled trial.

Allocation: concealed.*

Blinding: clinicians, patients, {data collectors, outcome assessors, data analysts, and monitoring committee}†.

Follow up period: 12 month follow up at 3 month intervals.

Setting: general practices in western and central Scotland, UK.

Patients: 259 patients ≥18 years of age (mean age 54 y, 58% women), who had been diagnosed with asthma for ≥1 year and were receiving ≥800 µg daily of inhaled beclomethasone dipropionate (or equivalent dosage of budesonide or fluticasone propionate). Exclusion criteria: need for oral corticosteroids, general practice visit or hospital visit for asthma in the past 2 months; inability to use a peak flow metre; treatment with immunosuppressive drugs; serious illness; alcohol, drug, or substance abuse; or pregnancy.

Interventions: step down group (n=130) or a control group (n=129). All patients received a pack containing inhaled corticosteroids at their regular dosage. Asthma control was assessed at 3, 6, 9, and 12 months. Patients in the step down group received a reduced dose if they had good control. Short acting β agonists were allowed in both groups.

Outcomes: asthma exacerbations (any worsening of asthma requiring oral corticosteroids). Secondary outcomes included asthma related events (hospital admission, emergency department visit, or general practice visit because of worsening asthma), and achieving a 50% reduction in inhaled corticosteroid dose.

Patient follow up: 1 year follow up was 82%; all patients were included in the analysis for the primary outcome.

*See glossary.

†Information provided by author.

MAIN RESULTS

Analysis was by intention to treat. Groups did not differ for asthma exacerbations or any asthma related events (table). 84% of the step down group and 81% of the control group had good control. 49% of patients in the step down group completed the study with a reduced dose of inhaled corticosteroids. Step down and control groups did not differ for oral corticosteroid use, but inhaled corticosteroid use was lower in the step down group (use for 1 y 390 v 517 mg, $p<0.001$).

CONCLUSION

In patients with chronic, stable asthma, inhaled corticosteroids were safely stepped down.

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Step down v usual dose (control) inhaled corticosteroids for chronic, stable asthma at 1 year*

Outcomes	Step down	Control	RRI (95% CI)	NNH
Asthma exacerbations	31%	26%	20% (–18 to 78)	Not significant
Hospital admission	3%	1%	297% (–39 to 2524)	Not significant
Emergency department visit	2%	1%	98% (–74 to 1405)	Not significant
General practice visit	35%	32%	8.9% (–23 to 54)	Not significant
			RRR (CI)	NNT
Home visit by general practitioner	2%	5%	50% (–77 to 86)	Not significant

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

Abstract and commentary also appear in *ACP Journal Club*.

Commentary

The dose response curve for inhaled corticosteroids is relatively flat with most of the benefit on commonly measured outcomes (symptoms, peak flow, or use of rescue medication) occurring at lower doses.¹ There may be a dose response effect in prevention of asthma exacerbation.

In a recent study, the rate of improvement in measures of asthma control with inhaled corticosteroids was determined over time.² In order, night time symptoms, pulmonary function, daytime symptoms, and use of short acting β agonists improved over 1–4 months. However, airway hyperactivity improved slowly and was still improving at 72 weeks. Such results raise the question of whether the dose of inhaled corticosteroids can be stepped down in patients with chronic, stable asthma and still maintain asthma control.

Hawkins *et al* designed a large, blinded study with 1 year of follow up to answer this question. This well done study showed that a substantial proportion of patients with chronic asthma (49%) could reduce their dose of inhaled corticosteroids by 50% without increasing either symptoms or exacerbations. One of the limitations of the study was that participants were advised to use their reliever inhaler on a “regular basis,” and no data were presented about changes in use of rescue medication after reduction of inhaled corticosteroids. It should also be noted that about one third of patients were maintained on long acting β agonists.

This study showed that a step down strategy can be used in patients with moderate or severe disease without compromising asthma control. Nevertheless, the fact that over half of the patients were unable to significantly reduce their dose of inhaled corticosteroids suggests that a conservative protocol² in stepping down inhaled corticosteroids may be warranted (eg, 25% reduction at 8 wk intervals and maintaining peak flow >85% of baseline).

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1 Barnes PJ, Pederson S, Busse WW. *Am J Respir Crit Care Med* 1998;**157**:S1–53.

2 Reddel HK, Jenkins CR, Marks GB, *et al.* *Eur Respir J* 2000;**16**:226–35.