Doubling the dose of inhaled corticosteroids during asthma deterioration did not improve asthma control


Clinical impact ratings GP/FP/Primary care ******************** IM/Ambulatory care ******************** Allergy ******************** Respirology ********************

In patients with asthma, does doubling the dose of inhaled corticosteroid (ICS) reduce the need for prednisolone when control starts to deteriorate?

METHODS

Design: randomised, placebo controlled trial.

Allocation: concealed. *

Blinding: blinded (clinicians and patients). *

Follow-up period: 12 months.

Setting: a hospital in Nottingham, UK.

Patients: 390 patients who were ≥16 years of age (mean age 49 y, 67% women) with a clinical diagnosis of asthma; were taking ICS, 100–2000 μg/d on a regular basis, and required oral corticosteroids or doubled their dose of ICS in the previous 12 months. Exclusion criteria: history of smoking >10 pack years or unstable asthma during a 2 week run in period.

Intervention: patients were stratified by entry ICS dose (low to moderate or high) and allocated to an active inhaler (n = 192) or a placebo inhaler (n = 198). Study inhalers were matched to patients’ regular ICS, type of inhaler, and dose. Patients were instructed to take their study inhaler for 14 days in addition to their usual treatment if their morning peak flow decreased by 15% from the mean peak flow, or if their daytime symptom score increased by 1 point on a 4 point scale from the median symptom score during the run in period. Patients recorded their peak flow and symptom scores for 28 days during which time they were started on 10 days of prednisolone, 30 mg/d, if asthma control deteriorated to a point at which they would normally start oral corticosteroids, or peak flow decreased by 40%.

Outcomes: need for prednisolone. Secondary outcomes were maximum decrease in peak flow and increase in symptom scores while receiving the study inhaler.

Patient follow-up: 91% (intention to treat analysis).

*See glossary.

MAIN RESULTS

207 patients (53%) started the study inhaler (54% active and 46% placebo). Groups did not differ for need to start prednisolone, independent of whether they required the study inhaler (relative risk reduction 3.5%, 95% CI –26 to 45; see table on website). Groups also did not differ for maximum decrease in mean peak flow or increase in symptoms scores while on the study inhaler (see table on website). The results were similar in patients taking a low to moderate ICS dose.

CONCLUSION

Doubling the dose of inhaled corticosteroids when asthma control begins to deteriorate did not reduce the need to start prednisolone and did not affect change in mean peak flow or asthma symptom scores.

Abstract and commentary also appear in ACP Journal Club.