Budesonide increased symptom free days in patients with recent onset mild asthma at an additional cost of US$0.42/day


Methods

**Design:** cost effectiveness analysis of a randomised controlled trial (Inhaled Steroid as Regular Therapy in Early Asthma [START] study).

**Allocation:** concealed†.

**Blinding:** blinded [patients, clinicians, data collectors, outcome assessors, data analysts, and monitoring committee]†. *

**Follow up period:** 3 years.

**Setting:** (499 sites in 32 countries)‡.

**Patients:** 7241 patients (mean age 24.9 years; 54% women; based on 7165 patients) who had received a diagnosis of asthma ≤ 2 years before randomisation and had mild persistent asthma (ie, 1 symptom such as wheeze, cough, or chest tightness per week, but not as often as every day, during the previous 3 months and airway reversibility). Exclusion criteria: significant comorbidity.

**Interventions:** budesonide (Pulmicort Turbuhaler, AstraZeneca, London, UK), 400 μg (200 μg for children < 11 years) once daily (n = 3642)† or usual care (n = 3599)‡. As appropriate, patients could receive other asthma treatments, including other inhaled or oral corticosteroids.

**Outcomes:** incremental cost effectiveness ratio based on patient reported symptom free days (SFDs). Medical resource use data included hospital days, emergency department visits, physician or nurse visits, and telephone calls to healthcare providers; asthma related drugs; and missed days of school or work. Estimates of costs and outcomes were discounted at an annual rate of 3% and presented in 1999 values.

**Patient follow up:** (95% of patients were included in the efficacy intention to treat analysis, and 100% were included in the cost analysis)†.

*: See glossary.
†: Information provided by author.

**MAIN RESULTS**

At the end of 3 years, patients in the budesonide group had a mean of 14.1 more SFDs/year than patients who received usual care. From a healthcare payer perspective, the additional cost in the budesonide group was US$0.42/day; the incremental cost effectiveness ratio was US$11.30 per SFD/year gained (95% CI $8.60 to $14.90). From a societal perspective, which included the costs of absences from work or school, the additional cost in the budesonide group was US$0.14/day; the incremental cost effectiveness ratio was US$3.70 per SFD/year gained (CI $0.10 to $8.00).

**CONCLUSIONS**

In patients with recent onset mild asthma, budesonide increased the number of symptom free days compared with usual care. From a healthcare payer perspective, the net cost of budesonide use was an additional US$0.42/day, whereas from a societal perspective, the additional cost was US$0.14/day.

**Commentary**

Some studies show that patients with asthma who are started on inhaled corticosteroids (ICSs) early might benefit more than those started later. Other studies have reported that the addition of ICSs in steroid dependent patients reduces costs and improves cost effectiveness in patients with moderate-to-severe asthma. Little is known about the cost effectiveness of ICSs in patients with mild asthma.

Sullivan et al evaluate the cost effectiveness of early intervention with budesonide in mild persistent asthma. Study strengths include the large sample, length of follow up, and a design that reflects a real world approach to patient care. The fact that steroids could be added during the study (31% of patients and 45% of control group patients) means that the effects of ICSs were underestimated. Weaknesses include the high number of patients who did not complete the 3 year follow up (approximately 25%, although only 5% were not included in the analysis), which likely reflects the difficulties of patient compliance in mild disease.

Interestingly, the mean number of SFDs gained per year was 5.6 for children and 20.0 for adults, although early intervention was more cost effective in the youngest age group. This relates to the lower cost of medication in children because of lower dosages. Although a societal cost of 14 cents/day appears to be a bargain for improving quality of life of patients with mild asthma, the data can be viewed from many perspectives. The cost to healthcare payers to prevent 1 severe exacerbation (number needed to treat [NNT] = 76) is about ($11 600/year)*; and the cost to prevent a life threatening episode (NNT = 572)* is about ($87 600/year)*. Nevertheless, this well done study emphasises that even low dose ICSs (1 puff/d of budesonide) can significantly improve asthma control and reduce severe exacerbations.

*Data provided by author.

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