Efficacy and cost benefit of inhaled corticosteroids in patients considered to have mild asthma in primary care practice


Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Inhaled corticosteroids (budesonide) for the prevention of asthmatic attacks and the reduction of associated symptoms.

Type of intervention

Economic study type
Cost-benefit analysis.

Study population
Adults aged 18 years and older, diagnosed with mild asthma, who were currently receiving bronchodilatory treatment to alleviate attacks. Additionally, their physicians judged that they did not require regular corticosteroid therapy. Patients had to have a more than 10% difference in recorded peak expiratory flow rates prior to and post bronchodilation.

Setting
Primary care, community and hospital. The economic analysis was conducted in Hamilton, Ontario, Canada.

Dates to which data relate
No dates were stated. The base price year used was not stated.

Source of effectiveness data
Effectiveness data were derived from a single study.

Link between effectiveness and cost data
Cost data was collected prospectively using the same population sample as in the effectiveness analysis.

Study sample
Patients meeting the inclusion criteria were recruited from patient records of seven primary care practices across Canada. Power calculations do not appear to have been used to determine the sample size, although statistical power is considered by the authors in their conclusions. There were 57 patients in the study: 20 patients in the placebo group and 17 and 20 patients in the 400 micro.g and 800 micro.g per day groups respectively. The mean age of patients were 36 (+/- 12.7) years in the placebo group, 32 (+/- 9.0) years in the 400 micro.g group and 37 (+/- 17.8) years in the 800 micro.g group. There were 9, 8 and 8 male patients in these three groups. Baseline peak expiratory flow rates for the three groups were 403 L/min. (placebo), 381 L/min. (400 micro.g) and 364 L/min. (800 micro.g).
Study design
This was a multi-centre, double blind, randomised controlled trial. Subjects were stratified on the basis of strategic or perennial allergy and they were randomly assigned to each of the three treatment groups using a computer program. The duration of follow-up was 16 weeks following commencement of treatment. 18 patients (32%) were lost to follow-up, 9 patients chose to discontinue treatment, 6 did not appear for follow up, one patient violated the treatment protocol and two were withdrawn because of a lack of treatment efficacy.

Analysis of effectiveness
The analysis of effectiveness was based on intention to treat. The primary health outcomes used were the number of asthmatic symptoms reported and peak flow measurements. The authors stated that there were no important differences in baseline clinical characteristics or demographic information for subjects in the three groups.

Effectiveness results
There was a statistically significant improvement in peak expiratory flow performance rates for patients receiving budesonide compared with those in the placebo group both before and after taking treatment in the morning and evening, (p<=0.05). The number of symptoms reported by patients was also significantly lower in the intervention groups compared with the placebo group by the end of 8 weeks for early morning symptoms (p<0.01) and 12 weeks for nocturnal symptoms, (p<0.001). Furthermore, more patients reported a reduced impact of asthma in the intervention groups than in the placebo group, (p=0.01).

Clinical conclusions
The results of the study suggest that the use of low dosages of corticosteroids for patients with mild asthma can be effective in disease management and treatment without causing any undue adverse events.

Measure of benefits used in the economic analysis
Monetary benefits. Benefits were estimated using a willingness to pay questionnaire completed upon entry and completion of the study. Initially subjects were asked to state how much they were willing to pay to avoid asthma and associated problems. At the end of the study patients were asked whether the impact of asthma was less, and their willingness to pay to continue with treatment for improved outcomes where appropriate.

Direct costs
The cost of drug therapy, use of bronchodilators and other health care services were estimated. Costs of drug therapy were taken from the Ontario Ministry of Health. The costs of hospital services were estimated using a local Ontario hospital costing model and similarly physicians’ fees were determined using the Ontario Hospital Insurance Programme. Quantities of resources used were observed during the study period. The price years used in the model were not stated. Discounting was not used: this was appropriate given the short duration of the intervention. Costs were determined from the perspective of a third party payer. The cost of drug dispensing was assumed to be the same for all groups and therefore were not included in the analysis.

Indirect Costs
Not included.

Currency
Canadian dollars (Can$).

Sensitivity analysis
Not reported.
Estimated benefits used in the economic analysis
The mean willingness to pay for treatment per patient to avoid asthma symptoms for the three groups was Can$6.25 (range: Can$5 - Can$10) for placebo, Can$23 (range: Can$12 - Can$50) for 400 micro.g of budesonide and Can$20 (range: Can$10 to Can$50) for 800 micro.g of budesonide. These differences were not significant.

Cost results
Total mean costs per patient during the trial period for the three groups, were Can$92.77 (placebo), Can$78.88 (400 micro.g budesonide) and Can$140.02 (800 micro.g budesonide). These costs took account of treatment for relief of asthma and adverse events.

Synthesis of costs and benefits
Over the course of the trial period (16 weeks) the additional benefits of 400 micro.g budesonide compared with placebo were Can$268 and in addition there were further cost savings of Can$13.89, totalling Can$281.89 Similarly when comparing the 800 micro.g treatment with placebo there were additional benefits of Can$220 but additional costs of Can$47.25, leading to a total cost benefit per patient of Can$172.75.

Authors' conclusions
Regular inhaled corticosteroid therapy for patients with mild asthma is both effective and cost beneficial compared with treatment by bronchodilators only. No significant difference in effectiveness was observed between the 400 micro.g and 800 micro.g doses, but this may have been due to the small sample size of the study. It may be possible that lower dosages may also be effective.

CRD COMMENTARY - Selection of comparators
A justification for the comparator used was provided as this represented a recommended care protocol for patients with mild asthma in Canada.

Validity of estimate of measure of benefit
Clinical benefits were determined using a well designed double blind randomised controlled trial. As the authors noted, recruitment difficulties led to a very small sample size which was not able to detect any significant changes between the two doses of budesonide with a sufficient degree of power. Dates for the clinical trial do not appear to have been reported.

Validity of estimate of costs
Adequate details of the sources of cost information were provided and estimates of costs were taken from quantities of resources used in the clinical trial. However, the price years used in the analysis do not appear to be stated. The study was conducted from the perspective of a third party payer and it might have been interesting to determine whether there were any costs to other groups in society such as patients themselves due to differences in the incidence of asthmatic symptoms.

Other issues
The results of the economic analysis may not be generalisable outside the specific patient population and treatment protocols may also vary elsewhere compared with those in Canada. Only adult patients were included in the analysis, yet asthma affects many children and further analysis may also wish to consider the potential impact of treatment upon this population.

Implications of the study
Further well designed economic evaluations conducted alongside clinical trials of different populations, including children, are required to further test the conclusions reached in this study. Attempts should be made to recruit a larger patient sample, and lower dosages of corticosteroid treatment may also be worth evaluating. Mechanisms to improve patient compliance with treatment may also be worth including in further analysis, given the high dropout rate in this study. Longer term trials are required to assess any adverse events and risks associated with use of inhaled corticosteroids.

**Source of funding**
Supported by Astra Draco Inc.

**Bibliographic details**

**Original Paper URL**
http://www.pulsus.com/Respir/home.htm

**Other publications of related interest**
Evans M F and Frank J. Efficacy and cost benefit of inhaled corticosteroids in patients considered to have mild asthma in primary care practice. Canadian Family Physician 1997;43:632-633.

**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Administration, Inhalation; Adult; Anti-Asthmatic Agents /therapeutic use; Anti-Inflammatory Agents /therapeutic use /economics; Asthma /drug therapy; Bronchodilator Agents /therapeutic use; Budesonide /therapeutic use /economics; Cost-Benefit Analysis; Glucocorticoids /economics /therapeutic use; Middle Aged; Primary Health Care; Treatment Outcome

**AccessionNumber**
21997000654

**Date bibliographic record published**
30/06/2000

**Date abstract record published**
30/06/2000