

Budesonide/formoterol proves its worth in COPD

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Chronic obstructive pulmonary disease (COPD) is a widespread, progressive disorder associated with episodes of worsening symptoms and recurrent exacerbations. High morbidity related to COPD takes its toll on patients' QOL, while inpatient mortality of 6–26% is associated with acute exacerbations. Thus, COPD represents one of the leading causes of morbidity and mortality worldwide, and exerts a sizeable impact on individuals, societies and healthcare budgets. In addition, unlike other diseases which seem to affect less well-off countries, the impact of COPD is most profoundly felt in wealthier countries, such as the US and Canada. Preventing acute exacerbations and improving patients' QOL is a major aim of COPD management. Another pertinent consideration concerning COPD management is the allocation of healthcare resources, making the examination of costs and outcomes for different therapies of great importance to healthcare payers. These issues were investigated by researchers in two studies presented at a poster session at the 13th Annual Congress of the European Respiratory Society (ERS) [September–October 2003; Vienna, Austria].

Budesonide/formoterol improves QOL at no extra cost . . .

Budesonide/formoterol in a single inhaler can improve health status with no significant difference in cost relative to either drug alone or placebo, and thus is "*most probably a cost-effective treatment*" for patients with COPD, suggest researchers from Sweden.(1)(*) They performed a cost-consequence analysis using data obtained from the 1-year, multinational Global Initiative for Chronic Obstructive Lung Disease (GOLD stages III–V) study. In the study, 1022 patients with COPD were randomised to receive two inhalations twice daily of either budesonide/formoterol [Symbicort] 160/4.5µg, budesonide [Pulmicort] 200µg, formoterol [Oxis] 4.5µg or placebo; 951 patients remained in the study for > 15 days and were included in the economic analysis. Unit costs from Belgium were used to compare healthcare costs between the four treatment options.

The analysis revealed a "*consistent pattern of significantly increased effectiveness*" in terms of mean reduction in the number of COPD exacerbations for budesonide/formoterol relative to the other treatment options, say the researchers. Moreover, improvements from baseline in FEV₁ and in total scores for the St George's Respiratory Questionnaire (SGRQ) were significantly greater among budesonide/formoterol recipients than among patients randomised to the other treatment options. Furthermore, there were no significant differences in costs for healthcare resources(**) between the four groups over the 1-year period [*see table*]. Budesonide/formoterol was associated with a total direct cost of 2522 euros, similar to that for budesonide, formoterol and placebo (2362, 3150 and 2135 euros, respectively). However, budesonide/formoterol was associated with the lowest numerical hospital costs of all the treatments, note the researchers.

A sub-analysis conducted among a group of 699 European patients confirmed the robustness of these results and demonstrated that "*the pattern remained the same in the treatment groups*", comment the researchers.

. . . and reduces the use of oral systemic corticosteroids

The use of budesonide/formoterol may also reduce the need for systemic corticosteroids associated with acute COPD exacerbations, and thus have "*beneficial safety implications for vulnerable COPD patients*", according to research conducted by a multinational team of investigators.(2) The team examined the efficacy of budesonide/formoterol for exacerbations of COPD requiring medical intervention with oral corticosteroids and/or antibacterials and/or hospitalisation due to respiratory symptoms. During the 2-week run-in period of the two GOLD studies, and prior to randomisation, all current preventive medication was withdrawn (both studies), and in study 2 only, patients received prednisolone 30 mg/day and two inhalations of formoterol 4.5µg twice daily to optimise treatment; terbutaline 0.5mg as-needed was allowed in both studies. Patients were consequently randomised to one of four treatment regimens as previously explained.

Due to a reduction in the number of acute COPD exacerbations, the use of oral corticosteroids was significantly reduced by budesonide/formoterol relative to the other treatment options in both studies. Moreover, the time to the first oral corticosteroid course was increased with budesonide/formoterol compared with placebo in both studies, and compared with formoterol or budesonide alone in study 2. In addition, budesonide/formoterol significantly reduced the number of days on corticosteroids versus placebo in both studies, and versus budesonide or formoterol alone in study 2.

*Two of the researchers were affiliated with AstraZeneca R&D, Lund, Sweden.

**including hospitalisations, healthcare visits and contacts, and study and concomitant drug acquisition

Mean direct costs for patients with COPD receiving treatment over 1 year Costs	Budesonide/formoterol	Budesonide	Formoterol	Placebo
(euros)^a	(n = 245)	(n = 243)	(n = 235)	(n = 228)
Total hospital cost	887	1424	1734	1873
Total ambulatory cost	51	44	40	62
Total medication cost	1584	883	1376	201

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^a Costs were based on Belgian unit costs.

1. Löfdahl C-G, Andreasson E, Svensson K, Ericsson Å. Budesonide/formoterol in a single inhaler improves health status in patients with COPD without increasing healthcare costs. *European Respiratory Journal Supplement 22 (Suppl. 45): 50* (plus poster) abstr. P433, Sep 2003
2. Calverley A, Cseke Z, Peterson S. Budesonide/formoterol reduces the use of oral corticosteroids in the treatment of COPD. *European Respiratory Journal Supplement 22 (Suppl. 45): 50* (plus poster) abstr. P436, Sep 2003

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