Cost-effectiveness of fluticasone propionate/salmeterol (500/50 micrograms) in the treatment of COPD


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.

CRD summary
The objective was to estimate the cost-effectiveness of the combination of fluticasone propionate and salmeterol compared with no maintenance treatment in chronic obstructive pulmonary disease. The authors concluded that both the combination and salmeterol alone were cost-effective compared with no maintenance treatment. The methods were satisfactory, but more details of how the clinical parameters were identified should have been reported. The results were reported in detail and, within the scope of the analysis, the authors’ conclusions appear to be valid.

Type of economic evaluation
Cost-effectiveness analysis, cost-utility analysis

Study objective
The objective was to estimate the cost-effectiveness of treatment with fluticasone propionate and salmeterol compared with no maintenance treatment, in chronic obstructive pulmonary disease (COPD).

Interventions
The COPD treatments were: combined fluticasone propionate (500µg) and salmeterol (50µg); fluticasone propionate (500µg) alone; salmeterol (50µg) alone; and no maintenance treatment or no controller therapy.

Location/setting
USA/out-patient secondary care.

Methods
Analytical approach:
A Markov decision analytic model was used to examine the cost-effectiveness of treating COPD patients. The time horizon was the lifetime of the patient. The authors reported that a third-party payer perspective was adopted.

effectiveness data:
The clinical and effectiveness data were derived from a number of published studies. Many of the main clinical and effectiveness parameters were from a three-year, randomised, placebo-controlled trial; the Towards a Revolution in COPD Health (TORCH) project. The primary endpoint of this trial was the three-year mortality and this was used as a model parameter. The model patient population was assumed to have similar age characteristics to the moderate-to-very-severe COPD patient population and the other characteristics were assumed to be similar to those of the trial population. Other important effectiveness parameters, such as the transition probability between moderate, severe, and very severe COPD were from the Lung Health Study.

Monetary benefit and utility valuations:
The utility estimates were from four published studies.

Measure of benefit:
The benefit measures were life-years and quality-adjusted life-years (QALYs) gained. As these benefits could be generated over the lifetime of the patient, future benefits were discounted at an annual rate of 3%.

Cost data:
The model only considered the marginal costs due to having a moderate or severe exacerbation. The costs of moderate exacerbations included the out-patient visits, emergency department visits, laboratory tests, supplies, X-rays, antibiotics, and corticosteroids. Resource consumption and unit costs for a moderate exacerbation were derived from the published literature, the Resource-Based Relative Value Scale (RBRVS), and clinical opinion. The costs of a severe exacerbation were from a published study, which used information from the NDCH health Hospital Patient Level Database. These costs included facility care, laboratory tests, room and board, and medication use. Annual drug costs were also included in the model, and were based on their wholesale acquisition price from the Red Book. All costs were adjusted to 2006 US dollars ($) using the medical component of the Consumer Price Index. As they could be incurred over the lifetime of the patient, future costs were discounted at an annual rate of 3%.

Analysis of uncertainty:
A series of one-way sensitivity analyses was performed to test whether the results were robust to variations in the model assumptions and specific parameters. The authors also performed a probabilistic sensitivity analysis by fitting gamma or beta distributions to all the model parameters. Analyses were then run 10,000 times, and the results were presented in a cost-effectiveness acceptability curve.

Results
The lifetime average cost per patient was $42,019 with fluticasone propionate and salmeterol, $29,439 with salmeterol, $23,727 with fluticasone propionate, and $18,986 with no maintenance therapy. The lifetime QALYs gained were 7.42 with fluticasone propionate and salmeterol, 7.24 with salmeterol, 6.58 with fluticasone propionate, and 6.74 with no maintenance therapy. The LYS gained were 10.09 with fluticasone propionate and salmeterol, 9.84 with salmeterol, 8.91 with fluticasone propionate, and 9.15 with no maintenance therapy.

The costs and benefits were combined in an incremental cost-effectiveness ratio (ICER; the additional cost per life-year gained) and incremental cost-utility ratio (ICUR; the additional cost per QALY gained). Compared with no maintenance therapy, the ICUR was $33,865 for fluticasone propionate and salmeterol and $20,797 for salmeterol. Compared with no maintenance therapy, the ICER was $24,530 for fluticasone propionate and salmeterol and $15,098 for salmeterol. Fluticasone propionate was dominated by no maintenance therapy, which means it was both more costly and less effective, both in terms of QALYs and life-years.

The results of the probabilistic sensitivity analysis showed that, assuming an acceptability threshold of $50,000 per QALY gained, the probability of fluticasone propionate and salmeterol being cost-effective when compared with no maintenance therapy was 77.6%.

Authors' conclusions
The authors concluded that the combination of fluticasone propionate and salmeterol, and salmeterol were cost-effective COPD treatments when compared with no maintenance treatment.

CRD commentary
Interventions:
The interventions were reported in detail and appeared to reflect the relevant treatment options in the authors' setting.

Effectiveness/benefits:
The effectiveness and clinical data were derived from published studies, but the methods used to identify these studies, such as a literature review, were not reported. This means it is not possible to determine if all the relevant data were included. The effectiveness and clinical parameters were reported including their base-case values and sources. Brief details of these sources were reported for the main effectiveness estimates.

Costs:
The perspective was explicitly reported and all the major cost categories and costs relevant to the third-party payer perspective appear to have been included. The authors adequately reported the sources for the unit costs and resource data and these included expert clinical opinion and published data. The resource use data relied heavily on expert opinion, which was a valid approach, but these estimates should have been assessed in the sensitivity analysis. The time horizon, discount rate, methods used to inflate the costs, and the price year were all adequately reported.
Analysis and results:
Information on the lifetime costs and outcomes was synthesised using a Markov model. The structure of the model was reported in detail, with a diagram. A series of one-way sensitivity analyses assessed whether the model was robust to changes in its parameters. A probabilistic sensitivity analysis was also undertaken and this is considered to be the gold standard in the UK when assessing overall model uncertainty. The results of the model were presented in detail, but sufficient details of the review that identified the effectiveness and clinical parameters were not reported. The incremental cost-effectiveness analysis did not compare the combination of fluticasone propionate and salmeterol with salmeterol alone, which means that it is not possible to determine if the combination was cost-effective compared with salmeterol. The authors acknowledged some limitations of their study, such as the assumptions needed due to a lack of data; and that the lifetime clinical data were based, in most cases, on three-year trial data. They advised caution on the generalisability of their findings to the wider population of COPD patients, given their reliance on one three-year clinical trial.

Concluding remarks:
Overall, the methods were satisfactory, but more details of how the clinical parameters were identified should have been reported. The results were reported in detail and, within the scope of the analysis, the authors’ conclusions appear to be valid.

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