Pharmacoeconomic evaluation of tiotropium bromide in the long-term treatment of chronic obstructive pulmonary disease (COPD) in Italy
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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
This study evaluated the cost-effectiveness of adding tiotropium bromide to the routine care for chronic obstructive pulmonary disease (COPD). The authors concluded that adding tiotropium to routine care was cost-effective for patients with moderate to very severe COPD, in Italy. The model was well constructed and used valid data. The authors’ conclusions appear to be appropriate.

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

Study objective
This study evaluated the cost-effectiveness of adding tiotropium bromide to the routine care for chronic obstructive pulmonary disease (COPD).

Interventions
Routine COPD care, consisting of beta-antagonists, corticosteroids, and other drugs, was compared with the same routine care plus once daily tiotropium bromide bronchodilator.

Location/setting
Italy/out-patient care.

Methods
Analytical approach:
A lifetime probabilistic patient-level simulation was created, with an annual cycle length. The model consisted of four mutually exclusive states corresponding to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) stages II, III and IV, and death. The patient characteristics were randomly assigned from a population distribution. The authors stated that they adopted an Italian health services perspective.

Effectiveness data:
The primary effectiveness data were from a large multicentre randomised controlled trial, the Understanding Potential Long-Term Impacts on Function with Tiotropium (UPLIFT) trial (Tashkin, et al. 2008, see ‘Other Publications of Related Interest’ below for bibliographic details). The main effectiveness data were the relative risks of mortality and exacerbations, and the differences in lung function and quality of life score.

Monetary benefit and utility valuations:
Health-related quality of life was recorded using St George’s Respiratory Questionnaire (SGRQ). The SGRQ scores were matched to the GOLD stages. The SGRQ data were mapped to the European Quality of life (EQ-5D) questionnaire to create health-related utility weights, using a published mapping algorithm.

Measure of benefit:
The measures of benefit were life-years gained and quality-adjusted life-years (QALYs). Benefits were discounted at a 3.5% annual rate.

Cost data:
The cost data were from a study of COPD in Italian referral centres, and Italian reimbursement tariffs. The costs included diagnostic and laboratory tests, doctor visits, hospitalisation, and drug and other therapy for routine care and COPD exacerbation care. The costs were adjusted to more closely match the characteristics of patients in the UPLIFT trial. All costs were in Euros (EUR) and a discount rate of 3.5% per year was applied.

Analysis of uncertainty:
Uncertainty was investigated by assigning probability distributions to each model parameter. These distributions varied according to the characteristics of patients that predicted progression between GOLD stages and to death. A scatterplot of the results was presented, as well as a cost-effectiveness acceptability curve.

Results
The model resulted in a 0.50 year gain in life expectancy for patients on tiotropium bromide, which was equivalent to 0.42 QALYs gained. The lifetime additional cost was EUR 3,360, resulting in an incremental cost-effectiveness ratio of EUR 7,916 per QALY gained.

At a willingness-to-pay threshold of EUR 7,500 per QALY gained the addition of tiotropium bromide was cost-effective, compared with routine care, in 40% of simulations. At a threshold of EUR 10,000 per QALY gained, it was cost-effective in 90% of simulations, and it was cost-effective in all simulations at a threshold of EUR 16,450 per QALY gained or higher.

Authors' conclusions
The authors concluded that the addition of tiotropium bromide was cost-effective for patients with moderate to very severe COPD in Italy.

CRD commentary
Interventions:
The principal intervention was adequately described. Routine care included a wide variety of interventions, accommodating variation in practice. The authors stated that other trials had not included treatments that might reduce the effectiveness of tiotropium bromide, but were taken by patients with COPD.

Effectiveness/benefits:
The effectiveness data were from the UPLIFT trial, which was a very large multicentre randomised controlled trial, with a pragmatic design. No systematic search for evidence was reported, but the trial appears to have been of high quality and a suitable choice. The model seems to have captured important outcomes, such as adverse events and changes in GOLD status. Converting the SGRQ scores to EQ-5D utilities allows the results to be generalised and increases their applicability for decision making. The utility data were well reported. All the utilities were adjusted to fit the population in the UPLIFT trial, which increases the concordance between the data. Italian population characteristics were used, where possible.

Costs:
All the costs were derived appropriately using Italian data. It appears that the costs of the relevant outcomes were captured and presented with sufficient detail. The costing methods will allow the replication of the model for alternative settings, but the price year was not presented.

Analysis and results:
The main incremental cost-effectiveness results were well reported. In the uncertainty analysis, it appears that only one stage of simulations was conducted, despite the fact that an individual-patient simulation was conducted. If this was the case, then the uncertainty in the results partially reflected the population variation. This means that the cost-effectiveness acceptability curve could be interpreted as the certainty that the intervention is cost-effective for a patient randomly drawn from the population, at different cost-effectiveness thresholds, rather than for an average patient.

Concluding remarks:
The model was well constructed and used valid data. The authors' conclusions appear to be appropriate.
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