Economic evaluation of sublingual immunotherapy vs symptomatic treatment in adults with pollen-induced respiratory allergy: the Sublingual Immunotherapy Pollen Allergy Italy (SPAI) study


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
The study investigated the use of sublingual immunotherapy (SLIT) in association with standard treatment in young adults with pollen-induced allergic rhinitis and asthma. This intervention was compared with standard treatment alone.

Type of intervention

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised young adults aged between 16 and 45 years with ascertained allergic rhinitis, with or without asthma, due to pollens.

Setting
The study setting was outpatient secondary care. The economic study was carried out in Italy.

Dates to which data relate
The dates during which the effectiveness and resource use data were derived were not reported. The price year was 2002.

Link between effectiveness and cost data
The costing was undertaken retrospectively on the same patient sample that provided the epidemiologic data.

Study sample
No sample size appears to have been determined in the planning phase of the study. Epidemiologic data were collected from the Retrospective Observation Physician Panel (ROPP), which comprised 27 physicians from 25 allergy centres. Each physician was responsible for collecting retrospective data from the clinical records of approximately 100 consecutive young adults. A total of 25 physicians completed and returned the study questionnaire. The 25 questionnaires summarised the data from 2,230 patients. The authors did not report how many of these patients were treated with SLIT plus standard care and how many were treated with standard care alone.

Study design
Epidemiologic data were derived from a retrospective cohort study undertaken in 25 allergy centres in Italy. The
authors did not report the timeframe during which the data were collected.

**Analysis of effectiveness**
The primary health outcome used was the number of cases that improved, worsened, or remained unchanged with or without SLIT. These data were then used to populate the decision tree model. As the authors provided no details of the two patient groups included in the study, it was unclear if the groups were comparable at analysis.

**Effectiveness results**
The authors did not report any effectiveness results that might have been derived from the ROPP.

**Clinical conclusions**
There were no effectiveness results from which to draw a clinical conclusion.

**Modelling**
A decision tree model was used to evaluate the costs and consequences of the two interventions. The five health states of the model were improvement, stabilisation, aggravation, inadequate response and asymptomatic. When building their model the authors assumed that:

the efficacy of SLIT was superior to that of current treatment;  
SLIT could modify the natural history of rhinitis;  
after 3 years of SLIT a long-term efficacy was maintained;  
for patients who discontinued SLIT after two pollen seasons, the efficacy was the same as that of standard treatment; and  
when a patient became asymptomatic, she/he continued SLIT treatment and stopped all drug therapy.

**Measure of benefits used in the economic analysis**
The measures of benefit used were the number of patients improved and the number of asthma cases avoided.

**Direct costs**
The direct costs to the NHS and those borne by the patients were included in the analysis. The costs included were for diagnostic tests (skin prick tests, IgE measurement and spirometry), medications (oral antihistamines, intranasal steroids and decongestants, intracocular cromones, inhaled steroids, inhaled short- and long-acting beta2-agonists, and oral corticosteroids), SLIT (including build-up and maintenance), medical visits and hospital admission due to asthma. The costs of medications were retrieved from the Italian National Drug Price List. The cost of SLIT was based on the dosing schedule recommended by the manufacturer. The number of follow-up visits was retrieved from the ROPP, and their unit cost was obtained from the National Ambulatory Tariff List. The cost of diagnostic tests was based on NHS tariffs. The number of hospital admissions was obtained from the ROPP analysis, and their unit costs were based on NHS tariffs. The authors conservatively assumed that the rate of hospitalisation was the same in both the SLIT and no SLIT groups.

Since the costs could be incurred during 6 years, discounting was relevant and was appropriately applied at an annual rate of 3%. The price year was 2002. The study reported the average costs. The unit cost of each resource use category was reported.

**Statistical analysis of costs**
The costs were treated as point estimates (i.e. the data were deterministic).

**Indirect Costs**
The authors included working days lost due to asthma, which were obtained from ROPP data. They did not, however, attribute any working day loss to rhinitis, whatever the severity. Productivity losses were valued on the basis of the 2002 gross salary of individuals with paid occupations in Italy divided by 220 working days per year. The price year was 2002.

**Currency**
Euros (EUR).

**Sensitivity analysis**
Sensitivity analyses were used to validate the model and to test the robustness of the modelling assumptions. They were performed by varying the patients' distribution by disease (i.e. rhinitis and/or asthma) and severity level, and the cost of hospitalisation.

**Estimated benefits used in the economic analysis**
Over 6 years, and for a cohort of 1,000 patients, symptoms were improved in 631 patients in the SLIT arm compared with 232 patients in the no SLIT arm. SLIT therefore improved the symptoms of 399 of 1,000 patients.

SLIT also prevented asthma in 518 of 1,000 patients, compared with 289 of 1,000 patients in the no SLIT arm. The difference was 229 patients per 1,000 patients.

**Cost results**
From an NHS perspective, the average discounted cost per patient during 6 years was EUR 1,901 in the SLIT group compared with EUR 2,408 in the no SLIT group.

From a societal perspective, the average discounted cost per patient during 6 years was EUR 4,313 in the SLIT group compared with EUR 6,426 in the no SLIT group.

**Synthesis of costs and benefits**
The costs and benefits were combined using an incremental cost-effectiveness ratio (i.e. the additional cost per patient improved and the additional cost per asthma case avoided). From both the NHS and societal perspectives, SLIT was found to be dominant over the no SLIT alternative treatment (i.e. it was both more effective and less costly).

The results of the sensitivity analyses showed that variations in disease and severity distributions and hospital admission costs did not alter the authors' findings, with SLIT remaining the dominant alternative.

**Authors' conclusions**
From the perspectives of both the National Healthcare System (NHS) and society, sublingual immunotherapy (SLIT) was less costly and more effective than pharmacotherapy alone.

**CRD COMMENTARY - Selection of comparators**
A justification was given for using pharmacotherapy alone as the comparator. It represented current practice in the authors' settings. However, the authors stated that SLIT was advantageous in comparison with subcutaneous immunotherapy (SCIT), but SCIT does not appear to have been included in the analysis. This might have been useful. You should decide if the comparator used represents current practice in your own settings.
Validity of estimate of measure of effectiveness
The analysis was based on a retrospective cohort study in which clinicians enrolled in the study reported the outcomes for 100 of their patients. This type of study is associated with some limitations, especially inclusion bias whereby patients most likely to benefit from the intervention are enrolled into the study in detriment to those who might benefit less. Since details of the study sample were not reported, it is not possible to establish if the study sample was representative of the study population or if the patient groups were comparable at analysis.

Validity of estimate of measure of benefit
The estimation of health benefit (i.e. the number of patients improved and number of asthma cases avoided) was derived using a decision tree model, with the results of the retrospective study being used to populate the model. The use of these benefit measures will hinder comparisons with the benefits of other interventions.

Validity of estimate of costs
The analysis of the costs was performed from both health care system and societal perspectives. It would appear that all the relevant categories of costs for these perspectives, and all relevant costs, were included in the analysis. Resource use was mainly derived from the retrospective study, whereas the unit costs were derived from published sources. Since the costs were incurred during 6 years, future costs were appropriately discounted. The authors performed a very limited sensitivity analysis of the costs in which only the costs of hospital admission were varied. The cost data were adequately reported, the authors reporting the price year (which will ease any future inflation exercises), the discount rate and the unit cost for each resource use. However, the costs and the quantities were not reported separately.

Other issues
The authors compared their findings with those from other studies which, in general, also found that SLIT was cost-saving over the long run. The issue of generalisability to other settings was not addressed. The authors do not appear to have presented their results selectively and their conclusions reflected the scope of the analysis. However, the authors should have provided more data on the effectiveness results reported in the ROPP in order to enhance the validity of the model's results. The authors reported no limitations to their study.

Implications of the study
The authors would appear to recommend the use of SLIT in addition to current treatment, as it was found to be cost-saving from both a health care system perspective and societal perspective.

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None stated.

Bibliographic details

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Other publications of related interest
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**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
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