Cost-effectiveness analysis of tacrolimus ointment versus high-potency topical corticosteroids in adults with moderate to severe atopic dermatitis

Ellis C N, Drake L A, Prendergast M M, Abramovits W, Boguniewicz M, Daniel C R, Lebwohl M, Paller A S, Stevens S R, Whitaker-Worth D L, Tong K B

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

High-potency topical corticosteroids (HPTCs) were compared with tacrolimus ointment for the treatment of atopic dermatitis (AD). The HPTCs under consideration were amcinonide, betamethasone, clobetasol, desoximetasone, diflorasone, fluocinonide, halcinonide, halobetasol and mometasone. Two different treatment cycles for HPTCs were considered, treatment for a 2-week consecutive period and for a 4-week consecutive period.

Type of intervention

Treatment.

Economic study type

Cost-effectiveness analysis.

Study population

The study population comprised adult patients with moderate to severe AD who were unresponsive to, or not well controlled with, mid-potency topical corticosteroids.

Setting

The setting was secondary care. Since the study was based on a model, a specific setting was not stated.

Dates to which data relate

The effectiveness data were derived from literature published between 1974 and 2001. The dates to which the unit costs and resource use related were not stated. The price year was not reported.

Source of effectiveness data

The effectiveness data were derived from a review of published material, augmented by both the authors' assumptions and expert opinion.

Modelling

A Markov model (DATA, Version 3.5, Treeage Software) was used to represent the periods of remission and relapse that patients encounter. The analysis considered simulated patients that the model randomly assigned to treatment groups.

Outcomes assessed in the review

The authors assessed the transition probabilities (probability of successful treatment) of HPTCs at 2 and 4 weeks, and tacrolimus at 2 and 4 weeks. For this purpose, the authors defined success using the number of disease-controlled days.

They considered the patients to be disease controlled if that patient achieved a greater than 75% improvement. The review also assessed the probability of continuing with tacrolimus after 4 weeks and the dosage per week.

Study designs and other criteria for inclusion in the review
The authors reported that they identified all articles of class I/II HPTCs for the treatment of AD. Articles were excluded if they did not use a physician global assessment of disease, did not have a minimum of 2 weeks' outcome data, and if they only examined paediatric patients.

Sources searched to identify primary studies
MEDLINE was searched using both the generic and brand names of the drugs.

Criteria used to ensure the validity of primary studies
Not reported.

Methods used to judge relevance and validity, and for extracting data
Not reported.

Number of primary studies included
Thirteen studies were included in the review.

Methods of combining primary studies
A meta-analysis was carried out. A measure of efficacy was estimated by calculating a weighted average of the efficacy data from all eligible studies. No further details of the meta-analysis were reported.

Investigation of differences between primary studies
Not reported.

Results of the review
The probability of successful treatment with HPTCs was 52% at 2 weeks and 64% at 4 weeks;

The probability of successful treatment with tacrolimus was 36% at 2 weeks and 52% at 4 weeks.

The probability of continuing with tacrolimus after 4 weeks was 80%.

The dosage per week was 17.5 g.

Methods used to derive estimates of effectiveness
The effectiveness estimates were supplemented by the authors' assumptions and expert opinion.

Estimates of effectiveness and key assumptions
The authors assumed that the probability of success of secondary treatment at 4 weeks was 0%. They also assumed that the relapse rate after disease improvement was 50% for topical HPTCs and50% for tacrolimus. Expert opinion was used to adjust the efficacy of HPTC to account for repeated use.

Measure of benefits used in the economic analysis
The summary measure of benefit was the total disease-controlled days (DCDs).

Direct costs
The costs were estimated from the perspective of the third-party payer over a horizon of one year. Discounting was not required. The authors estimated the costs of prescription drugs and physicians. The cost of over-the-counter medication was not included, as this was not relevant to the perspective adopted. The authors explicitly stated that they did not estimate the direct non-medical costs, such as transportation, or the cost of long-term side effects or adverse events. The unit costs were reported separately. The quantities were determined by a patient's progression through the modelled treatment pathways. The cost of HPTCs, tacrolimus and physician-related costs were derived from actual data (AWP and fee schedules). The cost of secondary treatment was assumed. The dates when the unit prices were collected were not stated.

Statistical analysis of costs
No statistical analysis of the costs was reported.

Indirect Costs
The authors explicitly stated that indirect costs such as productivity, time lost seeking treatment and quality of life, were not estimated.

Currency
The currency used for the costing was not explicitly stated. However, US dollars ($) appear to have been used.

Sensitivity analysis
A sensitivity analysis was used to explore the impact of intra-treatment DCDs on the cost-effectiveness.

Estimated benefits used in the economic analysis
The total number of DCDs was 185 for HPTCs in 2-week cycles, 194 for HPTCs in 4-week cycles, and 190 for tacrolimus ointment.

Cost results
The total cost of treatment was $1,682 for HPTCs in 2-week cycles, $1,317 for HPTCs in 4-week cycles, and $1,323 for tacrolimus ointment.

Synthesis of costs and benefits
The average cost per DCD was $9.08 for HPTCs in 2-week cycles, $6.80 for HPTCs in 4-week cycles, and $6.97 for tacrolimus ointment.

The authors did not estimate incremental cost-effectiveness ratios because "none of the therapies provided additional DCDs at additional cost". The authors reported that the model was sensitive to the relapse rate of patients being treated with tacrolimus ointment, and the costs and efficacy of secondary treatment.

Authors' conclusions
Tacrolimus ointment was more cost-effective if class I/II high-potency topical corticosteroid (HPTC) use was restricted to 2-week intervals. The cost-savings associated with tacrolimus offset the higher costs of the drug.

CRD COMMENTARY - Selection of comparators
The authors compared HPTCs with tacrolimus ointment. The authors justified the use of HPTCs as a comparator on the grounds that they were the most widely used treatment. However, this may not be the case in alternative settings. The reader should therefore assess whether these comparators would be relevant to their own setting.

Validity of estimate of measure of effectiveness
The authors did not state that a systematic review of the literature had been carried out. The effectiveness estimates were combined using a weighted average calculation that included all eligible studies. However, the authors did not report how the weights were determined. In addition, the authors did not discuss the impact of differences between the primary studies, although they did perform a sensitivity analysis to assess the impact of the probability of relapse and the efficacy of secondary treatment.

Validity of estimate of measure of benefit
The benefits were estimated using the Markov model to calculate the number of DCDs. This was appropriate for the objective of the study since it accurately reflected the cyclical nature of AD through remission and relapse. The authors gave a full justification for their choice of DCDs as the summary benefit measure.

Validity of estimate of costs
A third-party payer perspective was adopted for the costing analysis and the authors included the costs of drugs and physician visits. It appears that, for the perspective given, no relevant costs have been omitted. An analysis from a wider perspective, such as that of society, may have included the costs incurred by the patient and possibly altered the principle conclusions of the study.

Other issues
The findings were compared, appropriately, with published results. The authors discussed some of the limitations of the study including the omission of some of the costs. The issue of generalisability to other settings was not explicitly addressed, although the authors invited physicians to examine their own treatment regimens in the light of the sensitivity analyses reported. The authors did not present their results selectively. The conclusions drawn accurately reflect the results given and are relevant to the stated objective and the study design.

Implications of the study
The authors did not make any recommendations for policy or practice and did not highlight any areas for further work. They did, however, point out the lack of common end points in the evaluation of AD.

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