**Prednicarbate versus fluocortin for inflammatory dermatoses: a cost-effectiveness study**  
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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.

**Health technology**  
Prednicarbate versus fluocortin for the treatment of inflammatory dermatoses such as dermatitis and eczema.

**Type of intervention**  
Treatment.

**Economic study type**  
Cost-effectiveness analysis.

**Study population**  
Patients with inflammatory dermatoses, receiving non-occlusive treatment, for which prednicarbate and fluocortin were indicated (i.e. patients with psoriasis and other similar conditions were excluded). The clinical trials included subjects aged from under 1 to 90 years of age of both sexes.

**Setting**  
Outpatient clinic. The study was performed in Spain.

**Dates to which data relate**  
The effectiveness analysis data were from the years 1986 to 1996. The dates of the resource use data were not stated. 1996 price information was used.

**Source of effectiveness data**  
The evidence for final outcomes was based on a review of previously completed studies.

**Modelling**  
A decision tree was used to combine published evidence on effectiveness with resource use data relevant to Spain. The model included the costs associated with failure of initial therapy and adverse events and the costs of treatment.

**Outcomes assessed in the review**  
The effectiveness rate ('proportion of total patients cured or responding to treatment') and the incidence of adverse reactions ('ineffectiveness') were the health outcomes of interest to the authors of the review.

**Study designs and other criteria for inclusion in the review**  
The meta-analysis only included randomized, double-blind clinical trials, which included patients receiving non-occlusive treatment, and measurement parameters to estimate the global effectiveness of the treatments. The analysis
considered the treatment period lasting from 15 to 21 days as the standard period for the two forms of treatment.

Sources searched to identify primary studies
MEDLINE, references in review articles, and internal documentation and data from the laboratories of Hoechst Marion Roussell and Novag SA were searched.

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

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

Number of primary studies included
In total, 20 studies were used: 13 referred to prednicarbate, 4 to fluocortin and 3 published manuscripts were included.

Methods of combining primary studies
The study was based on a meta-analysis. A fixed effects quantitative analysis method was used to combine the results. The method used to assess the combined results was the Mantel-Haenszel technique as modified by Peto, to estimate the odds ratio of treatment success as a measure of frequency.

Investigation of differences between primary studies
Homogeneity tests were performed on the clinical trials combined in the meta-analysis. The trials included for prednicarbate were found to be homogeneous (chi square = 14.69; k=12; p=0.327) whereas the trials of fluocortin were observed not to be homogeneous (chi square = 9.9, k=3, p=0.012).

Results of the review
Prednicarbate and fluocortin were effective in 85.8% and 69.7% of patients respectively. The incidence of adverse reactions to prednicarbate was 3.5% compared to 4.9% for fluocortin. The value of a combined odds ratio for the combined studies of prednicarbate was 1.54 (95% CI: 1.10 - 2.15), and 0.73 (95% CI: 0.60 - 0.89) for fluocortin relative to moderate or moderate to high potency corticosteroids.

Measure of benefits used in the economic analysis
The additional number of patients achieving a therapeutic success (reduction of lesions by 50% or more) without experiencing adverse effects was used as the measure of benefits. The corresponding estimate of benefit was based on the endpoints associated with the results from the review upon which the effectiveness study was based.

Direct costs
Cost discounting was not used as it was irrelevant in the context of the study given that the window of analysis was well below 1 year. The cost boundary included the hospital’s costs and the patients’ costs. Quantities and costs were reported separately. The costs included were those relating to the initial treatment (price of the medicines) and costs associated with further treatment resulting from lack of response and adverse effects (including an additional visit to the physician). Out of pocket costs included were those of transport to the medical facility. The costs estimates were based on published information on acquisition prices from the National Health Authority and quantities were based on opinion (dermatologist’s recommendation). 1996 price data were used.
Indirect Costs
Cost discounting was not used as it was irrelevant for an analysis with a time frame below 1 year. Costs and quantities were reported separately. The costs measured were those associated with the value of lost working hours due to a second visit to the physician after lack of response to initial treatment or the onset of adverse effects. The estimate of the quantities was based on a guess and on census data taken from the Spanish National Institute of Statistics. 1991 price data were used.

Currency
Spanish Pesetas (Ptas). Ptas were converted to US dollars ($): $1= Pta.124 using 1996 values.

Sensitivity analysis
One-way sensitivity analysis was carried out varying the following parameters: clinical effectiveness of the alternatives, price of prednicarbate, incidence of adverse reactions, costs of ineffectiveness/adverse effects and treatment regimen.

Estimated benefits used in the economic analysis
The success rate per patient treated with prednicarbate was 82%, whilst that achieved with fluocortin was 66.6%. These figures imply an additional 15.4% success, i.e. 15 additional patients achieving therapeutic success with prednicarbate when compared with fluocortin for every 100 patients treated.

Cost results
The total cost per patient treated for prednicarbate and fluocortin was Pta4,600 ($37.10) and Pta5,778 ($46.60) respectively. The total expected cost per patient treated was Pta3,971 for prednicarbate and Pta4,608 for fluocortin, considering only the direct costs of treatment. The duration of the intervention was 21 days.

Synthesis of costs and benefits
An incremental analysis was unnecessary since prednicarbate was observed to result in higher benefits and lower costs than fluocortin, thus making it the dominant strategy. Using sensitivity analysis, if the clinical effectiveness of fluocortin was equal to 85%, then fluocortin should be equal to 90% to achieve the level of (average) cost-effectiveness ratio equal to prednicarbate. If the level of effectiveness of fluocortin equals 70%, the level of prednicarbate should be approximately 65% to be equal to the fluocortin level of (average) cost-effectiveness ratio. If the level of incidence of adverse effects are equal for both treatments, the cost of prednicarbate is lower than that of fluocortin. Similar analysis arrived at the same qualitative result, namely, that prednicarbate is a superior option to fluocortin and remains so over plausible ranges of parameter values in the model.

Authors' conclusions
Treatment with prednicarbate is both more effective and less costly than treatment with fluocortin.

CRD COMMENTARY - Selection of comparators
The comparator chosen was that of moderate and moderate-to-high potency topical corticosteroids, which were selected as reference treatments in view of their extensive use. The economic analysis only concentrated on the two most widely used corticosteroids for the treatment of inflammatory dermatoses in Spain.

Validity of estimate of measure of benefit
In general, the methods used in the effectiveness study were clearly described.
Validity of estimate of costs
As the authors acknowledged, the economic study suffered from the limitation implicit in considering as equivalent outcomes those associated with patients experiencing remission from symptoms and those of patients showing a marked improvement. The authors also argue the case for future measurement and inclusion of quality of life implications of treatments.

Other issues
Sensitivity analyses addressed the range of uncertainty in key parameters. The authors noted that the results are not generalisable to other countries and that they are valid only for the treatment of dermatoses which are at least moderately responsive to topical corticosteroids, citing the examples of dermatitis and eczema.

Implications of the study
This study is based on good clinical evidence and an economic model which has been observed to give clear, robust evidence on the economic implications and cost-effectiveness of the available therapeutic options for the treatment of inflammatory dermatoses moderately responsive to topical corticosteroids within the Spanish context. Further methodological improvements are needed to gain a more precise and clear description of benefits and cost-effectiveness in this field.

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