Medication formulation affects quality of life: a randomized single-blind study of clobetasol propionate foam 0.05\% compared with a combined program of clobetasol cream 0.05\% and solution 0.05\% for the treatment of psoriasis

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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
The study compared two treatment options for patients with psoriasis. The treatments were clobetasol foam (0.05\%) applied to the skin and scalp, and a combination of clobetasol cream (0.05\%) applied to the skin and clobetasol solution (0.05\%) applied to the scalp.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised adult patients with stable or worsening psoriasis covering at least 3\% of the body surface area (BSA), including both the skin and the scalp. No further exclusion or inclusion criteria were reported.

Setting
The setting was the community. The economic study was carried out in the USA.

Dates to which data relate
No dates relating to either the effectiveness or cost data were reported in the study.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
Although not explicitly stated, it appears that the costing has been performed prospectively on the same sample of patients as that used in the effectiveness analysis.

Study sample
The sample size was not determined in the planning phase of the study, and power calculations were not performed retrospectively. Initially, 7 women and 25 men (mean age 49 years) were enrolled in the study, all being residents of the San Francisco Bay area. Three patients were excluded and a justification for their exclusion was provided. The number of patients allocated to the two groups was not reported.
Study design
The analysis was based on a single-centred, single-blinded randomised study. The method of randomisation and the blinding method were not reported. The duration of follow-up appears to have been 14 days. However, to minimise interactions with prior treatments, washout periods of 2 weeks for topical agents and 4 weeks for oral medications were required. Three patients were excluded due to non compliance.

Analysis of effectiveness
The analysis was based on the study participants for whom data were available. The primary outcomes were psoriasis area, disease severity, and quality of life (QOL). Severity of disease was evaluated using the Psoriasis Area and Severity Index (PASI). This is a scoring index that weights the severity of three intensity measures (erythema, induration and scale) with percentage BSA affected. In addition, a self-administered PASI was used to evaluate the patients’ perception of their skin changes. The authors mentioned that reported compliance was similar in the two groups. Data were analysed for treatment completers only, using Excel software. Two-tailed tests were performed with p-values less than 0.05 being considered statistically significant. The authors reported that there were no statistically significant differences between the groups. Also, that the patients’ participation was not affected by their socioeconomic status, as the patients were distributed across different income groups and educational backgrounds.

Effectiveness results
The two treatments were equally effective in treating erythema, (p=0.33), induration, (p=0.12), and scale, (p=0.41).

For scalp psoriasis, the foam was more effective than the solution in both absolute, (p=0.03), and percentage terms, (p=0.03).

The clobetasol foam also demonstrated better results pertaining to pain associated with treated skin than the cream-solution combination, (p=0.02).

The clobetasol foam resulted in a mean decrease in PASI score of 5.0, while the cream-solution combination resulted in a mean decrease in PASI score of 3.3, (p=0.05).

The PASI score in the foam group decreased by 41% versus 35% in the cream-solution group, (p=0.17).

The percentage of BSA affected decreased by 3.4% in the foam group and by 2.8% in the cream-solution group.

Clinical conclusions
The authors concluded that clobetasol foam was generally more effective than the clobetasol cream-solution combination for the treatment of mild to moderate psoriasis.

Measure of benefits used in the economic analysis
The benefits used were the percentage of BSA treated and the change in PASI score. These were derived from the effectiveness results.

Direct costs
Treatment costs (i.e. cost per gram of medication used over the 2-week period) were included in the analysis. Resource use was derived directly from the effectiveness study, whereas the source of the cost data was not reported. Discounting was not performed, which was appropriate as the time horizon appears to have been less than 2 years. The dates relating to resource use or costs and the price year were not reported.

Statistical analysis of costs
Two-tailed tests were performed with p-values less than 0.05 being considered statistically significant.
Indirect Costs
The indirect costs were not included in the analysis.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The total costs for the two treatment options were not reported (see Synthesis of Costs and Benefits).

Synthesis of costs and benefits
The treatment cost per 1% BSA affected was $8.18 in the foam group versus $7.05 in the cream-solution group. This difference was not statistically significant, \( p=0.30 \).

The cost per 1-point change in PASI score was $21.60 in the foam group versus $16.42 in the cream-solution group. This difference was not statistically significant, \( p=0.20 \).

Authors' conclusions
The authors suggested that clobetasol foam was a better treatment than the clobetasol cream-solution combination for the treatment of mild to moderate psoriasis when considering the increased improvement in clinical severity, the decreased application time, and the increased perception of relative efficacy combined with similar treatment costs.

CRD COMMENTARY - Selection of comparators
The authors gave a justification for the choice of comparator. You should decide if this is a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on single-centred, single-blind, randomised study, which was appropriate for the study question. It is not possible to comment on the internal validity of the study since the methods of randomisation and blinding were not described. The study sample comprised patients with psoriasis and was appropriate for the study population. The patient groups were shown to be comparable at analysis.

Validity of estimate of measure of benefit
The primary measure of benefit (percentage change in BSA affected) was obtained from the effectiveness analysis. Severity of disease was evaluated using the PASI, while QOL was measured using the EuroQoL-5d questionnaire and Dermatology Life Quality Index (DLQI). Differences in QOL, as reported in the DLQI, were not statistically significant and this measure of benefit was not used in the economic evaluation.

Validity of estimate of costs
The authors did not explicitly state the perspective adopted in the study, but it was unlikely to have been hospital since the indirect costs were not included in the analysis. The only cost included in the analysis was the cost per gram of the medication used over the 2-week period, and this was not reported separately from the quantities used. The quantities of resources used were derived from the effectiveness analysis and no statistical analysis of the quantities used was performed. In addition, there was no sensitivity analysis of either the cost or quantities. This may limit the interpretation of the study findings.

Other issues
The authors compared their results with published studies, reporting consistency in most of the findings. The issue of generalisability to other settings was not discussed. The cost estimates and efficacy data appear to have been based on US estimates and, as there was no sensitivity analysis, the generalisability of the results may be limited. The study involved adult patients (older than 18 years) with psoriasis and this was reflected in the authors’ conclusions. The authors reported a number of further limitations to their study. First, the small sample size might have masked a true difference between the groups in terms of specific issues reported in the DLQI (i.e. dressing, swimming and difficulty applying medication). Second, the follow-up period (14 days) for which symptom improvement was evaluated was considered to be quite short, as it did not necessarily provide a change for the outlook, prognosis or restrictions on daily activities imposed by a lifelong condition.

The authors reported a conflict of interest in that one of them is a paid consultant for Connetics Corporation, which supported the research.

Implications of the study
The authors made no specific recommendations for changes in policy or practice. However, they stressed the fact that, for chronic conditions such as psoriasis, QOL status can be used to evaluate therapeutic efficacy. Therefore, they suggested that further investigation of the interaction among clinical effectiveness, QOL and cost would help professionals to evaluate therapeutic choices for psoriasis and other skin diseases.

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