Economic evaluation of maintenance treatment with tacrolimus 0.1% ointment in adults with moderate to severe atopic dermatitis

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 examined the cost-effectiveness of maintenance use (MU) of tacrolimus ointment versus its standard use, in adults with moderate to severe atopic dermatitis (AD). The authors concluded that MU was more effective and led to cost-savings, especially in patients with severe AD. On the whole, the study was well conducted and satisfactorily reported, although the issue of uncertainty was not addressed. The authors’ conclusions appear to be valid.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
This study examined the cost-effectiveness of maintenance use (MU) versus standard use (SU) of tacrolimus ointment in adults with moderate to severe atopic dermatitis (AD).

Interventions
Maintenance treatment with tacrolimus 0.1% ointment twice a week for one year was compared with the SU of the ointment twice a week for one year.

Location/setting
Germany/primary care.

Methods
Analytical approach:
This economic evaluation was based on a single study with a one-year time horizon. The authors stated that the analysis was carried out from the perspectives of the third-party payer, the patient, and society.

Effectiveness data:
The clinical data were derived from a phase III, multinational, double-blind, randomised controlled trial (RCT) which involved patients with moderate or severe AD from 22 centres in 13 European countries. From the 224 patients enrolled in the trial, 134 patients provided valid and complete data. There were 75 patients in the MU group (43 with moderate AD and 32 with severe AD) and 59 in the SU group (35 with moderate AD and 24 with severe AD). The length of follow-up was one year and the primary clinical endpoint was the number of disease exacerbations.

Monetary benefit and utility valuations:
The utility values were based on Short Form (SF-36) data from the sample of patients enrolled in the RCT. The utility values were assessed upon entry to the study and at the end of follow-up (one year).

Measure of benefit:
The benefit measures were the number of disease exacerbations and the change in quality of life between baseline and the end of the treatment, for the two groups.

Cost data:
The economic analysis included the costs of drugs, non-drug therapies, physician visits, hospital out-patient visits, in-patient stay (including rehabilitation), diagnostic procedures, disease-specific expenses (e.g. dust mite prevention),
emollients and skin care products, self-medications, co-payments for prescriptions, expenses for transport to the physician or the hospital, additional child care, and productivity losses because of absence from paid work. The resource use data were derived from case reports, completed by patients enrolled in the RCT, every two months during the disease control period. Missing values were estimated using the mean values stratified by disease severity. The data on resource use were pooled from all patients in all countries. Whenever possible, these items were costed using German national sources, such as the German pharmaceutical index for drugs, and the German diagnosis-related groups for hospital costs. The costs for out-patient visits were provided by means of telephone research. Productivity losses were valued using the human capital approach and gross wage data. The price year was not explicitly reported and all costs were in Euros (EUR).

Analysis of uncertainty:
The issue of uncertainty was not addressed.

Results
For moderate AD patients, from the perspective of the third-party payer, the mean total costs per patient were EUR 1,274 (standard deviation, SD: ± 1,048) for MU and EUR 1,116 (SD: ± 961) for SU. From the perspective of the patient and the family, they were EUR 247 (SD: ± 214) for MU and EUR 318 (SD: ± 348) for SU. From the perspective of society, they were EUR 1,525 (SD: ± 1,081) for MU and EUR 1,729 (SD: ± 1,209) for SU. These differences did not reach statistical significance.

For severe AD patients, from the perspective of the third-party payer, the mean total costs per patient were EUR 1,612 (SD: ± 1,237) for MU and EUR 2,632 (SD: ± 1,366) for SU. From the perspective of the patient and the family, they were EUR 245 (SD: ± 263) for MU and EUR 257 (SD: ± 216) for SU. From the perspective of society, they were EUR 2,045 (SD: ± 2,013) for MU and EUR 2,904 (SD: ± 1,510) for SU. The total costs were significantly lower in the MU group from the third-party payer perspective, but not from the societal perspective.

The number of disease exacerbations was lower in the MU group than in the SU group (moderate AD: 2.4 for MU, 5.5 for SU, severe AD: 2.3 for MU, 7.4 for SU) and these differences reached statistical significance, especially in patients with severe AD.

The quality of life in the MU group increased significantly from 0.71 to 0.79 in patients with moderate AD and from 0.66 to 0.75 in patients with severe AD. In the SU group, the changes in quality of life were not statistically significant.

A synthesis of the costs and benefits was not required given the dominance of MU, which was simultaneously more effective and less expensive than usual care.

Authors' conclusions
The authors concluded that MU was more effective and led to cost-savings in comparison with SU of tacrolimus, especially in patients with severe AD.

CRD commentary
Interventions:
The selection of the interventions was appropriate and reflected the comparison between a maintenance treatment approach and the current recommended use of tacrolimus.

Effectiveness/benefits:
The clinical data were derived from an RCT, which is usually considered to be a good source of evidence given its robust design. The study groups were comparable at baseline with respect to their demographic and clinical characteristics. The double-blind design and the multi-centre setting further enhance the study validity. A possible limitation was the fact that a subgroup of the original sample was selected for this analysis, due to the exclusion of patients with mild disease, who did not receive tacrolimus treatment. This might have reduced the power of the study. The instrument used to elicit the patient preferences for quality of life is a validated tool.

Costs:
The analysis of costs was extensively described. The use of three separate perspectives enhances the relevance of the economic analysis for different payers. The cost categories were consistent with each perspective. Furthermore, the authors provided extensive information on the resource consumption for all items. The approach used for missing data was described, and the sources of data were reported for all items. The price year was not reported, which may reduce the possibility of replicating the analysis for other time periods. A drawback was that the issue of uncertainty around the cost estimates was not investigated. The authors noted that the main limitation was the use of resource use estimates from data pooled from several European countries, which might not reflect the German treatment patterns.

Analysis and results:
The authors did not combine the economic and clinical endpoints of the analysis, given the dominance of one strategy over the other. The issue of uncertainty was not investigated and sensitivity analyses were not carried out. The results of the analysis were clearly presented and discussed.

Concluding remarks:
On the whole, the study was well conducted and satisfactorily reported, although the issue of uncertainty was not addressed. The authors’ conclusions appear to be valid.

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