THE COST-EFFECTIVENESS OF ISOTRETINOIN IN PATIENTS WITH MODERATE-TO-SEVERE ACNE VULGARIS

Hany Tohy
University of Southern California, Los Angeles, CA, USA

OBJECTIVES: To assess from a societal perspective whether isotretinoin (13-cis-retinoic acid) or oral antibiotics in combination with topical preparations is the more cost-effective first-line treatment of moderate-to-severe acne vulgaris. METHODS: A decision-tree model was used to simulate therapy costs and effectiveness. All estimates of cost and effectiveness were obtained from the literature or expert opinion. The cost-effectiveness ratio was reported as incremental cost per quality-adjusted life-year (QALY) gained. The time horizon was 2 years. Costs and QALYs were discounted by a mortality rate of 0.0023%, which was assigned an arbitrary rate to be adjusted to 2009 US dollars. A one-way sensitivity analysis was used to determine the robustness of the model's results. The model was developed using Microsoft Excel. RESULTS: Isotretinoin increased discounted costs by $1,486 and discounted QALYs by 0.071 years when compared to the treatment therapy of oral antibiotics and topical preparations. This resulted in an incremental cost-effectiveness ratio (ICER) of $20,930 per QALY gained for the base case. The results of the model were insensitive to most model parameters except for the probabilities associated with achieving adequate response or relapse while on therapy. The biggest change in the ICER (204% increase) was caused by a 17% increase in the probability of maintaining adequate response (no relapse) with conventional therapy. Although the ICER was sensitive to these probability values, the highest ICER value of $63,602/QALY found from the sensitivity analysis was still below the threshold for cost-effectiveness. CONCLUSIONS: Isotretinoin was more costly and also more effective than conventional therapy. These results did not change when model parameters were varied in the sensitivity analysis. Assuming a $120,000/QALY threshold for cost-effectiveness, isotretinoin was cost-effective in the first-line treatment of moderate-to-severe inflammatory acne.
ANALYSIS FROM THE ACCEPT TRIAL

Most efficient in terms of cost/efficacy is adalimumab. Of the biologic agents authorized in Spain for treating moderate-severe psoriasis, the PASI 75 response. In the sensitivity analysis, adalimumab remains as the most cost-effective than etanercept 50 mg biweekly and therefore a preferable alternative in the treatment of moderate to severe plaque psoriasis in Turkey.

EFFICIENCY (COST/EFFICACY) OF BIOLOGIC AGENTS IN THE TREATMENT OF MODERATE TO SEVERE PSORIASIS

Lázaro B, Blasco A, Ferrándiz C, García A, Liso J

OBJECTIVES: To estimate the cost/efficacy ratios of biologics authorized in Spain in 2009 (adalimumab, etanercept, infliximab and ustekinumab) in the management of moderate-severe psoriasis. METHOD: A model for economic evaluation (decision tree) was built for the treatments according to the available scientific evidence. The payer perspective (National Health System) was used, only considering drug cost and assuming zero cost for placebo. In the case of weight-dependent dosing, the weight of the patients was set, and the US wholesale acquisition cost (WAC) was adjusted by age and sex using the standard Spanish pharmacy cost corrected by the weight increment in individuals with psoriasis. The Psoriasis Area and Severity Index (PASI) 75 criterion (improvement of 75% from baseline PASI) was used as an indicator of efficacy. The incremental cost (calculated as the proportion of patients responding with PASI 75 criterion in the biologic group minus the proportion in the group who respond in the placebo group) was assigned according to the outcomes of clinical trials at the period of time defined in the primary efficacy outcome. When more than one trial was available per treatment, a meta-analysis was undertaken (DerSimonian-Laird method). Uncertainty was tested by deterministic sensitivity analysis, building scenarios with the confidence intervals at 95% for costs and efficacy. RESULTS: The incremental cost in the baseline scenario ranged from 31.19% (etanercept: 25 mg twice a week) to 78.34% (infliximab: 5 mg/kg at 24 weeks of treatment). The efficacy of the biologic agents used in Spain for treating moderate-severe psoriasis, the most efficient in terms of cost/efficacy is adalimumab.

COST PER RESPONDER OF USTEKINUMAB VERSUS ETANERCEPT IN PATIENTS WITH MODERATE-TO-SEVERE PLACQUE PSORIASIS: ANALYSIS FROM THE ACCEPT TRIAL

Feldman SR, Augustin M, Martin S, Stappy P, Schedel B

OBJECTIVES: To compare the cost per responder of ustekinumab (UST) versus etanercept (ETN) based on head-to-head data from the ACCEPT trial, which demonstrated greater efficacy of two doses of UST, 45 mg and 90 mg at weeks 0 and 4, versus ETN, 50 mg twice weekly through week 12, in patients with moderate-to-severe plaque psoriasis (PsO). METHODS: Efficacy results (proportion of patients achieving at least 75% improvement in the Psoriasis Area and Severity Index [PASI75]) were obtained from the ACCEPT trial (n = 903). Given the unique dosing of UST (weeks 0, 4, 16, and q12 weeks thereafter), we determined the cost per PASI75 response at week 16, the appropriate decision point for determining whether to proceed with a third dose. Week 16 PASI75 results were assumed to be equal to week 12 efficacy from ACCEPT; previously published randomized controlled trials have reported similar observations for both drugs. Dosing through week 12 was per ACCEPT. Dosing for weeks 13–16 was assumed to be per labeled indication in PsO. US wholesale acquisition cost (WAC) was used for calculating costs. The analyses used weight-based efficacy results for UST (45 mg ≤100 kg and 90 mg >100 kg) and overall efficacy for ETN to align with the respective approved labels for each drug. RESULTS: In ACCEPT, 209 patients received UST 45 mg, 347 received UST 90 mg, and 347 received ETN. Baseline demographics and disease characteristics were comparable between groups. Twenty-eight percent of patients were >100 kg. The PASI75 responses at week 12 were 72% for UST 45 mg in patients ≤100 kg and 65% for UST 90 mg in patients >100 kg, compared with 57% for the ETN group. At week 16, the US WAC per PASI75 response was $17,009 for UST-treated patients and $19,140 for ETN-treated patients. CONCLUSIONS: WAC per PASI75 response was lower for UST relative to ETN through 16 weeks in PsO patients.

COST-UTILITY ANALYSIS OF MAINTENANCE TREATMENT WITH TACROLIMUS OINTMENT IN ADULTS AND CHILDREN WITH MODERATE AND SEVERE ATOPIC DERMATITIS

Chauvin C, Bortolin A, Corrêa M, Krause O, Verma S, Dharmarajan S, Yang Y

OBJECTIVES: A twice weekly maintenance treatment strategy with tacrolimus ointment for atopic dermatitis significantly delayed and reduced the number of disease flares over a model, ustekinumab compared with the standard reactive tacrolimus treatment strategy. The aim of this post hoc analysis was to evaluate the cost-effectiveness of the maintenance strategy versus the reactive strategy in adults and children with moderate and severe atopic dermatitis (AD). METHODS: The evaluation was performed using a decision analytic model based on the results of two pivotal phase III trials that were conducted in adults and children receiving 0.1% and 0.03% tacrolimus ointment, respectively. Clinical data were taken from the clinical trials and utility data were derived from a published source. The time horizon was 12 months; costs and utilities were applied to the treatment periods only and were extrapolated in the 12-month period post-tacrolimus discontinuation. Sensitivity analyses assessed the degree of uncertainty around the results. The analysis was conducted from the perspective of the UK National Health Service. RESULTS: In the base-case analysis for both adults and children with moderate and severe AD, the maintenance treatment strategy with tacrolimus ointment was dominant over the reactive treatment strategy in that it was more effective and less costly. In univariate sensitivity analyses, for all patient groups, few parameters when varied between the value of their upper and lower confidence interval resulted in the maintenance treatment strategy being no worse or better than the reactive treatment strategy in adults and children with severe AD and 54% for children with moderate AD and 54% for children with severe AD. CONCLUSIONS: Maintenance use of tacrolimus ointment is a dominant treatment strategy compared with reactive use, providing incremental health benefits at a lower cost.

MODELING THE COST-EFFECTIVENESS OF USTEKINUMAB FOR MODERATE TO SEVERE PLACQUE PSORIASIS IN US

Verma S, Dharmarajan S, Yang Y

University of Mississippi, University, MS, USA

OBJECTIVES: To determine cost-effectiveness of ustekinumab in patients with moderate-to-severe plaque psoriasis in comparison with Etanercept from third-party payer perspective. METHODS: A cost-utility analysis was performed using a Markov model which compared cost per QALY of Ustekinumab (45 mg at week 0 and 4, then every 12 weeks thereafter) and Etanercept (50 mg twice weekly for 12 weeks, then once a week). The probabilities of treatment response were taken from the ACCEPT trial (which compared both the drugs); while utility values for different stages were obtained from published studies. A 12 week paradigm for the base case of each agent was developed on the basis of dosage administration, laboratory monitoring utilized in the Randomized Clinical Trials and manufacturer’s published guidelines. The cost of therapies included 2009 AWP (average wholesale price) of both the drugs, and cost of physician visits and lab were inflated to 2009 from 2006 Medicare clinical laboratory fee schedule and physician reimbursement schedule (which is used to mean US reimbursement). Since the time frame of the analysis was only 12 weeks, the costs of long-term side effects and adverse events were not included. Extrapolations were made to calculate the cost-effectiveness of two drugs over a period of five years, with costs and benefits discounted at 3.5% per annum. Various sensitivity analysis were made to evaluate the cost-effectiveness of two drugs over a period of five years, with costs and benefits discounted at 3.5% per annum. Various sensitivity analysis were carried out to test the robustness of the model. RESULTS: The QALYs gained by Ustekinumab in comparison to Etanercept over a period of 5 years were 0.23, at an incremental cost-effectiveness ratio (ICER) of $63,493.59 per QALY gained. Further sensitivity analysis confirmed the robustness of results. CONCLUSIONS: Although as per the present analysis, Ustekinumab might not appear to be more cost effective than Etanercept, but it may be recommended due to modest increase in QALYs and convenient dosage pattern of once in 12 weeks.

SENSORY SYSTEMS DISORDERS – Patient-Reported Outcomes Studies

VALIDITY AND RELIABILITY OF THE VISUAL FUNCTION QUESTIONNAIRE UTILITY INDEX IN INDIVIDUALS WITH AGE-RELATED MACULAR DEGENERATION

Choi K, Patrick D, Kowalski J, Sullivan S

University of Washington, Seattle, WA, USA, *Aflerian, Irvine, CA, USA

OBJECTIVES: The Visual Function Questionnaire Utility Index (VF-UVI) is a vision-specific, preference measure developed from the National Eye Institute Visual Function Questionnaire 25. (NEI VFQ-25). The objective of this analysis was to assess the validity and reliability of the VF-UVI in individuals with aged-related macular degeneration (AMD). METHODS: Post-hoc analysis using data collected from a multicenter, randomized controlled trial of 138 individuals with AMD. The NEI VFQ-25, HUI and EQ-SD were administered at baseline and at day 1. The NEI VFQ-25 dataset was used to calculate utility values using the VF-UVI algorithm. Validity was assessed using convergent validity with HUI2, HUI3 and visual acuity and discriminant validity with the EQ-SD and known groups of visual acuity. Reliability was...