center, cross-sectional cost-of-illness study. Information as demographic characteristics, consultations, hospitalizations, rehabilitations, out-of-pocket-expenditures as for OTC-medication, copayment, skin care products and absence from work was collected with a semistandardized patient-questionnaire. Resource utilization of outpatient care was gained from patients' records. Direct and indirect costs were considered. RESULTS: 16 centers-10 office-based dermatologists, 4 office-based pediatricians, 1 outpatient unit of a dermatology hospital and 1 patient organization participated. Until now, 189 patients were enrolled at the medical centers. 153 patient questionnaires were sent back (including 53 from patients of the patient organisation). Mean age of patients is 24 years (1-71 years) and about 46% are male. About 27% of the patients have a mild course of disease, about 36% a moderate and about 37% a severe or very severe course of disease. Six out of 153 patients were hospitalized due to the current flare (4%). On average, patients' expenses for OTC-medication and skin care products are €164 per year, for additional treatment e.g. psychotherapy or naturopathy €62 per year and for e.g. special clothes or nutrition €349 per year. CONCLUSIONS: Because the study is still ongoing, annual cost data from the third party payers' perspective is under evaluation, and will be finalized not later than August 2002. But these preliminary results show that patients and their families bear are remarkable amount of the annual costs (about €575) by themselves.

#### PES 14 COST EFFECTIVENESS OF PIMECROLIMUS (ELIDEL) IN THE TREATMENT OF CHILDREN WITH ATOPIC DERMATITIS Grueger J, van Assche D

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**OBJECTIVE:** To compare the cost-effectiveness of an Elidel (pimecrolimus cream 1%) in the long-term management of children with atopic dermatitis. METHODS: Data were taken from a double-blind, multicenter, randomized, parallel-group study. Patients were randomised (2:1) to receive pimecrolimus treatment paradigm (i.e. emollients, pimecrolimus, medium potency topical corticosteroids) or standard of care (emollients, vehicle, medium potency topical corticosteroids). The study was conducted in children and adolescents (2 to 18 years of age, 474 patients on pimecrolimus and 237 patients on standard of care). Costs were estimated by linking severity of disease as defined by Investigator's Global Assessment (IGA) to average treatment costs. Drug costs were estimated from the clinical trial data. Efficacy was measured in number of patients with 0 flares over 12 months ("successfully treated patient", STP) and average number of flares as reported in the clinical trial. RESULTS: In the children and adolescent study, 68.4% of patients on pimecrolimus and 43.5% of patients on standard of care had no flare over the total study period of 12 months, a difference of 24.9%. The average number of flares in the pimecrolimus treatment group was 0.48, compared to 3.36 in the standard of care group, a reduction of 2.88 flares. Patients on pimecrolimus cost GBP 1009, patients on standard of care GBP 448, an incremental cost of GBP 561 over 12 months. 4.0 patients needed to be treated to achieve one STP, the cost per STP was GBP 2255 and the cost per flare avoided was GBP 195. The results were sensitive to the assumption of drug substance used, which is closely linked to the cost of treatment. **CONCLUSIONS:** Pimecrolimus has a very reasonable cost-effectiveness as measured by the incremental cost per additional successfully treated patient and the incremental cost per flare avoided.

#### EAR, EYE & SKIN DISEASES/DISORDERS—Clinical Outcomes

**PES 1 5** 

## USING A DISCRIMINANT FUNCTION TO MODEL THE LONG-TERM VISUAL FIELD CONSEQUENCES OF IOP CONTROL: A CASE STUDY BASED ON A TIMOLOL, LATANOPROST AND TRAVOPROST CLINICAL TRIAL

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**OBJECTIVE:** To estimate and compare the long-term consequences of IOP control of travoprost, latanoprost and timolol. METHOD: Daily IOP average, variance, minimum, and maximum were derived from a 12-month randomised, double-masked double-dummy, phase III multi-centre clinical trial comparing travoprost 0.004% od, latanoprost 0.005% od and timolol 0.5% bid. Patients had POAG or OH, and IOP was measured at weeks 2, 12, 24 and 48 at 8:00 am, 10:00 am and 4:00 pm. The Stewart discriminant functions were applied followed by a step-by-step threshold responder analysis. The statistical unit was eye and a second interaction order analysis of variance was performed including eve, time, treatment, and investigator as variables. Sensitivity analysis was performed on the 5th to 95th-percentile range of the discriminant empirical distribution function. **RESULTS:** Five hundred and ninety-six patients were randomly assigned to travoprost, timolol, or latanoprost. Travoprost patients' daily IOP average was significantly lower than timolol (-1.3 mmHg, P < 0.0001) and latanoprost (-0.3 mm Hg, P < 0.001). Similar results were found on daily IOP minimal value (respectively -1.3 mm Hg, P < 0.0001; -0.3 mmHg, P < 0.004) and daily IOP maximal value (respectively -1.5 mmHg, P < 0.0001; -0.3 mm Hg, P < 0.02). No difference was found on IOP variance between the prostaglandins (P < 0.25) while timolol patients had a higher estimate (-0.60; P < 0.004). If eight timolol patients were treated instead with latanoprost, one new VFD would be avoided over five

years. If 25 latanoprost patients were treated instead with travoprost, one new VFD would be avoided over 5 years. CONCLUSION: According to our model, the better control of both mean IOP and IOP variance by travoprost should better preserve patient vision. Prospective data collection should be performed to confirm our findings.

## MEDICAL OUTCOME OF GLAUCOMA TREATMENT IN FRANCE

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OBJECTIVE: To estimate the medical outcome of glaucoma/ocular hypertension (OH) treatment in France according to usual practice. METHODS: Ophthalmologists selected at random had to include 4 consecutive patients older than 18 seen in consultation during a week, 2 with glaucoma and 2 with OH. Socio-demographics, general and eye comorbidities, glaucoma risk factors, visual acuity (VA), papilla, and visual fields were collected. A visual field defect (VFD) was defined as a deterioration of papilla exam and visual field since diagnosis. A treatment switch was defined as adding a new drug or changing any of the current treatments. Time to failure of a treatment regimen, broken out by the number of treatment switches, was compared using the likelihood ratio applied to survival curves. RESULTS: One hundred and twenty seven of the 337 patients included by the 84 ophthalmologists had their full treatment documented from diagnosis. Twelve patients developed a new VFD after diagnosis (average follow-up: 2.5 years). No statistically significant difference on the known confounding factors of VFD was found between patients with and without VFD. Patients with VFD had a lower VA (-1.23; P < 0.08). At 3 years, 2.7% of the patients with no treatment switch had a VFD, compared to 22.6% with one treatment switch and 46.3% with >2 treatment switches. The difference between the three groups was statistically significant (P < 0.01). CONCLUSION: Patients with fewer treatment switches have less VFD. Under isotropic hypotheses, effective treatment strategies should be used first line in order to avoid visual field defect and therefore protect long-term patient vision.

#### PSORIASIS AND DEPRESSIVE SYMPTOMATOLOGY

PES 1 7

PES 16

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Skin diseases have a strong impact on physical and mental well-being of the patient. These diseases can appear at any age and, generally speaking, they have a greater repercussions on the quality of life of women. Dermatological conditions often alter the patient's own body image, which can cause psychological problems such as depression, anxiety and even suicide. OBJECTIVE: To evaluate the depressive symptomatology (DS) of patients with psoriasis. The CES-D (Center for Epidemiologic Studies-Depression scale), a short self-report scale composed of 20 items, is a questionnaire designed to measure DS in the general population. The CES-D is widely used in epidemiological surveys on large populations. METHOD: One thousand five hundred CES-D questionnaires were sent via a psoriasis patients support group: the APLCP. The questionnaires once completed were sent back trough a prepaid envelope. RESULTS: Six hundred thirty-seven questionnaires were returned: response rate: 42.5%. The sex ratio Men/Women was 46/54. Mean age: 48.9 years. Mean age of diagnosis: 25.7 years. The average to the total score was 20.9 (sd:12.5). The preliminary results showed DS in 48% of patients with psoriasis (versus 19% in the general population). There is DS in 47.1% of men and 49.0% of women. Two groups were identified: flare-up of psoriasis (46.7%), psoriasis not in flare-up (51.8%)-no answers (1.5%). Current episode of psoriasis are linked with higher frequency of DS (54.3% versus 42.4%). Psoriasis had a greater impact on patients with episode: CES-D score: 22.8 (sd:12.74) than patients without present episode CES-D score : 19.22 (s.d :11.96). This difference was significant (p < 0.0003). CONCLU-SION: Psoriasis patients have an increased risk of DS compared to the general population (48% versus 19%). A recent episode of psoriasis results in a more important frequency of DS in patients (54.3% versus 42.4%). Appropriate disease management and any treatment that could reduce flare-up frequency would improve patients' quality of life and help them face their psoriasis.

# EAR, EYE & SKIN DISEASES/DISORDERS—Quality of Life/Utility

PES 18

# VISION RELATED QUALITY OF LIFE OF FRENCH PATIENTS IS AFFECTED BY TOPICAL GLAUCOMA TREATMENT SIDE EFFECTS

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**OBJECTIVES:** To evaluate the consequences of local anti-glaucoma drug side effects on the vision-related quality of life of French patients. **METHODS:** A mail survey was sent to 20,000 homes belonging to the Sofres panel (representative of the French population according to the quota method) asking whether one member of the family was treated with one of the available topical anti-glaucoma drugs. A computer-assisted telephone interviewing system was used to confirm self-reported glaucoma treatment, to describe the disease and its treat-