period: In the period of four as well as eigth – weeks course of treatment with imiquimod 5% cream, therapy resulted in significantly higher chance of achieving complete clearance. Patients treated with imiquimod more frequently achieved clearance level higher than 75% of baseline actinic keratoses compared with the subject in vehicle group. Adverse events were more frequently recorded within the group of subjects who received imiquimod in comparison with vehicle group. The chance of experiencing local skin reaction such as erythema, flaking/scaling/dryness, scabbing/crusting, oedema, vesicles, erosin/ulceration was significantly higher in experimental group. Imiquimod five percent cream versus vehicle in long time period: Imiquimod 5% cream used 3 times a week for 24 weeks was an effective treatment for actinic keratosis measured by the probability of achieving complete clearance and partial clearance rate (more than 75% reduction in baseline lesions). Frequency of adverse events and local skin reactions was higher during the imiquimod treatment in comparison with placebo. Imiquimod five percent cream versus vehicle in patient with solid organ transplants: Treatment with imiquimod 5% cream for 24 weeks in kidney, heart and liver transplant patients resulted in significantly higher probability of achieving complete and partial clearance rates of actinic keratoses. There were no significant differences in incidence of adverse events between groups. **CONCLUSIONS:** Imiquimod five percent cream appears to be effective and safe alternative therapy for the treatment of actinic keratoses.

PSS5

RESTOR® VERSUS ACRILISA® : ND-YAG LASER INCIDENCE RATE COMPARISON 18 MONTHS AFTER SURGERY

Gauthier L[1], Lafuma A[2], Laurendeau C[3], Berdeaux G[4]

[1]Polyclinique Côte Basque Sud, Saint jean de Luz, France, [2]Cemka, Bg la reine, Hauts de Seine, France, [3]Cemka-Eval, Bourg-la-Reine, France, [4]Conservatoire National des Arts et Métiers, Paris, Hauts de Seine, France

OBJECTIVES: The aim of this study was to compare the 18 months Nd:Yag laser incidence rate of two multifocal intra-ocular lenses, ReSTOR® and Acrilisa®, implanted by a single surgeon following his usual practice. **METHODS:** This retrospective study was based on all patients implanted with a ReSTOR® or Acrilisa® multi-focal lens since Q3–2004 at one site. All patients with either cataract or clear lens were operated by the same surgeon. Medical data were obtained from patient charts. 18-months post surgical data were obtained from the surgeon's medical files and from other ophthalmologists, if involved in post-surgical care. Time to Nd:Yag laser analysis was carried out using Kaplan-Meier survival curves. Imbalance on confounding variables was adjusted with a Cox model. **RESULTS:** Eighty patients (160 eyes) were bilaterally implanted with ReSTOR® and 76 (152 eyes) with Acrilisa®. Patients with ReSTOR® were more often male (52.5% versus 30.7%; $P < 0.01$) and younger (63.1 versus 65.8; $P < 0.01$). After one year of follow-up, 3.6% of the ReSTOR® eyes had Nd:Yag laser versus 6.8% of the Acrilisa® eyes. After 18 months, the incidence rates were 4.6% and 26.0%, respectively ($P < 0.0001$). Age was weakly associated with Nd:Yag laser ($p = 0.09$). Eyes with Acrilisa® had 5.62 [2.64–14.02; $P = 0.0002$] more chances to have Nd:Yag laser than ReSTOR®. This persisted after adjusting on age [Hazard Ratio: 6.61; 2.61–16.76; $P < 0.0001$]. **CONCLUSIONS:** This analysis conducted at 18 months suggested that following usual surgical practice, ReSTOR® eyes had significantly less capsulotomy than those implanted with Acrilisa®. Young population were slightly more exposed at Nd:Yag laser. Analyses at two and three years will be required to confirm these findings.

PSS6

CONJUNCTIVAL HYPERAEMIA ASSOCIATED WITH THE FIXED COMBINATIONS OF LATANOPROST/TIMOLOL AND BIMATOPROST/TIMOLOL IN THE TREATMENT OF OCULAR HYPERTENSION OR GLAUCOMA

Vinuesa MJ[1], Vinuesa I[2], Díaz S[3], Martin I[3], Soto J[3], Fernandez-Arias I[3]

[1]Salamanca University, Salamanca, Spain, [2]Hospital Punta de Europa, Algeciras, Cádiz, Spain, [3]Pfizer, Madrid, Spain

OBJECTIVES: To assess the association of conjunctival hyperaemia with the fixed combinations of latanoprost/timolol (LT/TM) and bimatoprost/timolol (BM/TM) in the treatment of ocular hypertension or glaucoma using a systematic review and meta-analyisis of randomized clinical trials (RCTs). **METHODS:** A systematic search for RCTs published between 2000 and 2009 was conducted in Medline, Embase and Controlled Trials Register databases. The outcome measured was the appearance of conjunctival hyperaemia in studies comparing the use of either LT/TM or BM/TM versus different therapeutic options. Statistical analysis was performed including the calculation of odds ratio (OR) and its respective confidence interval, along with the inter-trial statistical heterogeneity. A sensitivity analysis was also carried out. **RESULTS:** A total of 16 RCTs comparing LT/TM versus distinct therapeutic alternatives and 5 CT comparing BM/TM versus different therapeutic options fulfilled criteria to be included in the meta-analysis. Although heterogeneity of both comparisons was not very high in both the LT/TM group ($Q = 24.47$; $p = 0.057$; $I^2 = 38.7$ %) and the BM/TM group ($Q = 5.19$; $p = 0.268$; $I^2 = 22.94$ %), the estimation of the OR by the random effects model was considered the most appropriate. According to this model the final OR for the LT/TM group was 0.56 (IC95%: 0.37–0.83), $p < 0.05$ and for the BT/TM group the OR was 0.94 (IC95%: 0.66–1.34), $p > 0.05$. In the sensitivity analysis performed, none of the RCTs included in this meta-analysis had an important effect in the global estimation of OR. **CONCLUSIONS:** According to available data, the use of LT/TM is associated with a significant reduction in the development of conjunctival hyperaemia versus the comparators used in the RCTs, whereas the use of BM/TM produces a conjunctival hyperaemia rate similar to its comparators.

PSS7

THE APPLICATION OF DISCRETE EVENT SIMULATION TO QUANTITATIVE RISK BENEFIT ANALYSIS

Maguire A[1], Douglas I[2], Blak BT[3]

[1]United BioSource Corporation, London, London, UK, [2]London School of Hygiene and Tropical Medicine, London, UK, [3]CSD EPIC, London, UK

OBJECTIVES: To date, quantitative risk benefit has mainly involved the translation of Cost-Effectiveness techniques or utility adjusted epidemiological statistics. We aim to describe how Discrete Event Simulation "DES" offers the possibility of modelling the occurrence of several adverse events and beneficial events simultaneously whilst accounting for competing events. **METHODS:** Firstly, a longitudinal patient database is used to identify the target patient population. Secondly, incidence rates for the outcomes are calculated from the entire database, thereby providing the necessary granularity in terms of the predictive factors for the outcomes. The annual probability for each outcome is then assigned to each patient in the cohort and DES generates time to each event. Thereby the expected events for an unexposed patient cohort is created to which relative risks are applied to model drug exposure. An example using glaucoma patients is presented using data from The Health Improvement Network. **RESULTS:** We obtained data on 17,652 glaucoma patients who were known to be receiving glaucoma therapy at January 1, 2007. Patients were characterised according to the principal determinants of the outcomes (heart failure, asthma/COPD exacerbation). The same database provided general population incidence rates for the outcomes which were assigned to each patient according to their characteristics. National statistics provided death rates. The expected events over one year for a cohort of 10,000 glaucoma patients were: HF = 95; asthma/COPD = 143; deaths = 605. **CONCLUSIONS:** These expected numbers represent the occurrence of events in the natural history cohort. They were obtained by summing the outcome probabilities across the patient group. They do, however, represent the first step in creating a comprehensive method for risk-benefit quantification via DES and large patient databases; benefit can be modelled if expressed as the occurrence of an event. The method will need to incorporate uncertainty in all the input parameters and to update the probabilities after an event has occurred.

SENSORY SYSTEMS DISORDERS – Cost Studies

PSS8

COSTS-OF-ILLNESS OF ULCUS CRURIS IN GERMANY: RESULTS OF TWO APPROACHES

Purwins S[1], Augustin M[1], Herberger K[1], Debus S[2], Rustenbach SJ[1]

[1]University Clinics of Hamburg, Hamburg, Germany, [2]Asklepios Klinik Harburg, Hamburg, Germany

OBJECTIVES: Estimation of cost-of-illness (COI) of leg ulcers in two German cross-sectional studies using different methodical approaches. **METHODS:** A direct and an indirect method for cost estimation were utilized. In a nationwide cross-sectional study in 33 specialized dermatological, surgical and general-medical wound centres, resource consumption and associated costs of venous leg ulcer(s) were collected directly from physicians and patients. In a second cross-sectional regional study, involving 147 institutions (hospitals, residencies, nursing services, dermatological offices, services for homeless and addictives) treating patients with ulcus cruris, resource consumption and associated costs were inferred from history, wound condition and actual/previous treatments based on standardized cost categories. Main economic parameters in both studies were direct, indirect and intangible costs (health related quality of life, HRQoL) from the societal perspective. **RESULTS:** The national study enrolled n = 218 patients with a mean age of 69.8 years (regional study: n = 502, 71 years). Wounds existed for 7 (regional 9) years on average. The mean total COI per year and patient was €9,569 (€10,624). While direct costs summed up to €8658 (€9851), indirect costs were much lower €911 (€772). Of direct costs, €7631 (€9122) were covered by the Statutory Health Insurances (SHI) and €1027 (€730) by the patients. For SHI, major cost factors were inpatient costs, non-drug treatments and physicians/nurses fees. Moreover, clinical predictors such as wound size, number and duration as well as wound etiology and characteristics of care (quality, support) were identified. All patients were severely impaired in their HRQoL, implying a high burden of disease and relevant intangible costs. **CONCLUSIONS:** Chronic leg ulcers generate highly relevant COI. Despite different recruitment and cost estimation methods, both studies resulted in comparable direct, indirect and intangible costs; observed differences can be attributed to sample characteristics. The results point to early and qualified disease management in all related health services areas.

PSS9

COSTS OF PATIENTS WITH OCCUPATIONAL SEVERE CHRONIC HAND ECZEMA REFRACTORY TO TOPICAL CORTICOSTEROIDS FOR EMPLOYER'S MUTUAL INSURANCE COMPANIES IN SPAIN

Mascaro JM[1], Querol I[2], Lindner L[3], Prior M[3], Oliver J[4], Halbach RP[4]

[1]Servicio de Dermatología Hospital Universitario Clínic, Barcelona, Spain, [2]Servicio de Dermatología MAZ, Zaragoza, Spain, [3]IMS Health, Barcelona, Spain, [4]Basilea Pharmaceuticals Iberia SL, Madrid, Spain

OBJECTIVES: To estimate the direct and indirect costs of occupational severe chronic hand eczema (OSCHE) in patients refractory to topical corticosteroids from the perspective of employer's mutual insurance companies (EMIC) in Spain. **METHODS:** An employer's mutual insurance company in Spain usually covers 75% of salaries and 100% of medical treatments of patients on occupational sick leave. A decision analytic