and the sensitive impairment of quality of life significantly contribute to the high socioeconomic burden of AD.

PSK6

BELGIAN DRUG UTILISATION STUDY OF ELIDEL® IN ROUTINE PRACTICE IN ATOPIC DERMATITIS

Lecomte P[1], Lambert J[2], Degreef H[3], Lesaffre E[4], De Backer M[1]
[1]Novartis Pharmaceuticals, Vilvoorde, Belgium, [2]UZ-Antwerpen, Antwerpen, Belgium, [3]UZ-St Rafaël, Leuven, Belgium, [4]Biostatistical Centre KULeuven, Leuven, Belgium

OBJECTIVES: To assess the impacts of Elidel® (pimecrolimus) cream 1% usage, in routine Belgian clinical practice in patients with mild to moderate atopic dermatitis, in terms of: pimecrolimus drug consumption; use of topical corticosteroids; quality of life; and safety. **METHODS:** An open-label, single arm, observational, multicenter study with one year follow-up to cover the seasonality of atopic dermatitis. Yearly pimecrolimus drug consumption was estimated based on the number and quantity of delivered prescriptions and on the number of unused or partially used tubes left at the end of the study. Topical corticosteroid use was assessed by a steroid usage questionnaire and the delivered topical corticosteroid prescriptions. Quality of life was gauged using validated disease specific instruments, i.e. the Parents'Index Quality of Life-Atopic Dermatitis (PIQoL-AD) or the Quality of Life Index-Atopic Dermatitis (QoLIAD), depending on patient's age. All adverse events were recorded. **RESULTS:** A total of 416 patients were enrolled from 49 study centers geographically spread over Belgium. For patients who completed this 12 months study, the mean (SD) amount of prescribed pimecrolimus cream 1% per patient was 120.8 (117.0) gram per year, with an estimated consumption of 104.4 (117.6) gram per year. Topical corticosteroids were used before the study in 81.7% of the population. At the end of study 83.3% of them stated that they were using less topical corticosteroids when pimecrolimus is part of their treatment regimen. Mean (SD) improvements versus baseline in PIQoL-AD and QoLIAD scores were 34.5% (84.3%) and 31.2% (70.8%), respectively. Median (IQR) improvements were 50.0% (12.5%–85.7%) and 46.4% (0.0%–85.0%), respectively. Pimecrolimus also showed good tolerability profile. **CONCLUSIONS:** This observational study showed favorable pimecrolimus profile in routine practice reflected by relatively small amount of drug used, corticosteroid sparing effect, improvement in quality of life, and good tolerability.

PSK7

CONVERGENT VALIDITY AND SENSITIVITY TO CHANGE OF GENERIC AND DISEASE-SPECIFIC INSTRUMENTS USED IN CHILDREN WITH ATOPIC DERMATITIS

Scalone L[1], De Portu S[2], Casati A[3], Colonna C[4], Monzini MS[1], Gelmetti C[4], Mantovani LG[2]
[1]Centre of Pharmacoeconomics, Milan, Italy, [2]University of Naples, Federico II, Naples, Italy, [3]Centre of Pharmacoeconomics, Milan, Italy, [4]IRCCS Policlinico, Hospitals Mangiagalli & Regina Elena Foundation, Milan, Italy

Generic Quality of Life (QoL) instruments are useful to compare different populations. However these instruments could be criticized for having some drawbacks, and disease-specific instruments could be preferred to measure those aspects of wellbeing influenced by a specific disease and to effectively measure health changes over the time. **OBJECTIVE:** We tested convergent validity and sensitivity to change over time of a generic and disease-specific pediatric questionnaires to evaluate wellbeing in children with Atopic Dermatitis (AD), a very frequent, chronic and disabling disease. **METHODS:** Data from the Costi-&-Outcomes-in-Dermatite-Atopica (CODA) naturalistic, prospective Cost-Of-Illness study, involving moderate and severe AD patients, were used. Patients aged 5–16 y.o. and/or their caregivers completed twice (at flare-up and after 2 months) the KINDL (children-reported version: KINDL-C, parent-reported version: KINDL-P; scores = 0–100, higher score = higher QoL) and CDLQI (Children's-Dermatology-Life-Quality-Index, with scores = 0–30, higher score = lower QoL). Patients' clinical status was evaluated with the SCORAD index (SCORing-Atopic-Dermatitis, possible score = 0–100, higher score = higher severity). We tested convergent validity by investigating correlations between QoL instruments; sensitivity to change over time was tested with paired students' t tests, Standardized Response Mean (SRM), Effect Size (EF). **RESULTS:** Pediatric patients were 66, 43.9% male, median age = 8.8 y.o., median SCORAD at enrolment = 41.5 (3.0–85.0). CDLQI significantly correlated with KINDL-P (Spearman's $r = -0.44$ $p = 0.001$) and KINDL-C ($r = -0.36$ $p = 0.008$), KINDL-P sensitively correlated with KINDL-C ($r = 0.67$ $p < 0.0001$). At follow-up clinical severity significantly decreased (Student's paired t test, $p < 0.0001$). Patients reported significant lower scores of CDLQI (Student's paired t test, $p < 0.05$), while no statistical change was found with KINDL-P and KINDL-C. SRM and ES were moderate for CDLQI (SRM = 0.44, ES = 0.41) and low for KINDL-C (SRM = 0.26, ES = 0.26) and KINDL-P (SRM = 0.12, ES = 0.11). **CONCLUSION:** KINDL significantly correlated with CDLQI, anyway sensitivity to change results were moderate to low. Understanding these properties in QoL questionnaires is necessary to allow their appropriate use and interpretation of QoL data.

PSK8

CONVERGENT VALIDITY AND SENSITIVITY TO CHANGE OF THE GENERIC INSTRUMENT EQ-5D AND THE DISEASE-SPECIFIC DLQI IN ATOPIC DERMATITIS

Scalone L[1], De Portu S[2], Casati A[3], Baranzoni N[4], Monzini MS[1], Giannetti A[4], Mantovani LG[2]
[1]Centre of Pharmacoeconomics, Milan, Italy, [2]University of Naples, Federico II, Naples, Italy, [3]Centre of Pharmacoeconomics, Milan, Italy, [4]Policlinico Hospital, University of Modena and Reggio Emilia, Modena, Italy

Generic instruments such as EQ-5D are useful to compare quality of life (QoL) of different populations and to include QoL information in health-economic research. However these instruments could be criticized for having some drawbacks, and disease-specific instruments could be more capable to measure those aspects of wellbeing influenced by a specific disease and could be more sensitive to measure health changes over the time. **OBJECTIVE:** We tested convergent validity and sensitivity to change over time of EQ-5D and the Dermatology-Life-Quality-Index (DLQI, possible scores = 0–30, higher score = lower QoL) in Atopic Dermatitis (AD), a very frequent, chronic, sensitively disabling disease. **METHODS:** Data from the Costi-&-Outcomes-in-Dermatite-Atopica (CODA) naturalistic, prospective, Cost-Of-Illness study, involving moderate and severe AD patients, were used. Socio-demographic, clinical severity (with SCORAD, SCORing-Atopic-Dermatitis index, possible score = 0–100, higher score = higher severity), economic and QoL data were collected. Patients from 16 y.o. self-completed twice (at flare-up and after 2 months) EQ-5D and DLQI. We tested correlation of EQ-5D indexes with DLQI and sensitivity to change over time of these indexes with paired Students' t tests, Standardized Response Mean (SRM), Effect Size (EF). **RESULTS:** Patients were 98, 48% male, median age = 30.5 y.o. (18–77). At enrolment median SCORAD = 53.0 (18.4–90.0), median EQ-VAS = 65.0 (0.0–95.0), median utility score from EQ-profile =