

used, thus confirming external validity. The mean score calculated from the ABS is  $48.17 \pm 18.36$ . The score increases with the severity of the AD. A statistically significant difference is observed between the 3 severity-groups, i.e. mild, moderate and severe, with scores of 30.63, 42.55 and 62.62 respectively. **CONCLUSIONS:** The internal and external validity of our Q were confirmed. ABS is correlated with the severity of AD. Hence, we have a short, easy-to-use, validated tool for assessing the burden imposed by atopy on families. Following cultural and linguistic validation, the ABS is now available in US English, Spanish, German and Italian.

#### PSS41 HEMANGIOMA FAMILY BURDEN: CREATION OF A SPECIFIC QUESTIONNAIRE

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**OBJECTIVES:** The notion of individual burden, associated with the disease, has been introduced recently to determine the "disability" caused by the pathology in the broadest sense of the word (psychological-social-economic-physical). The aim of our study is to develop a specific questionnaire for assessing the burden on families of children with HI. **METHODS:** A "Hemangioma Family Burden" questionnaire (HFB) consisting of 22 items, the score increases with the heaviness of the burden. It was distributed accompanied by 2 validated QoL questionnaires (SF12 and PGWB) to obtain internal and external validation. **RESULTS:** A total of 58 evaluable Q were returned. One parent from each family described how they perceived the effects of the disease, which led to the creation of 6 severity groups, paired together for size reasons: "not-very-far-reaching" and "somewhat-far-reaching"; "quite-far-reaching" and "far-reaching"; "very far-reaching" and "extremely far-reaching". Internal validity was measured by Cronbach's alpha, which is equal to 0.95, reflecting a good homogeneity of the 22 Q items. The mean scores of the physical and mental components are  $54.93 \pm 5.12$  and  $40.49 \pm 11.28$  respectively. Hence, the HFB score is correlated with these 2 components, thus confirming external validity. The mean score calculated from the HFB is  $23.42 \pm 19.93$ . The score increases with the "severity score" of the parents. In fact, a statistically significant difference is observed between the 3 severity groups:  $5.28 \pm 6.8$  for those reporting the smallest extent to  $41.0 \pm 18.71$  for those reporting the greatest extent, and  $27.7 \pm 16.96$  for a moderate extent. This confirms the sensitivity of the HFB. **CONCLUSIONS:** During the evaluation, internal and external validity were confirmed. The HFB is correlated with the extent felt by parents, a feeling deemed relevant because it is often the cause of consultation and demand for treatment. We now have an easy-to-use, validated IH tool for assessing the disability caused. Following cultural and linguistic validation, the HFB is now available in US English, Spanish, German and Italian.

#### PSS42 A SYSTEMATIC REVIEW OF PATIENT REPORTED OUTCOMES IN GLAUCOMA

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**OBJECTIVES:** Patient reported outcomes (PRO) are becoming useful tools for collecting and generating evidence for new medical products to show improvements in health-related quality of life (HRQoL). Glaucoma is a chronic disease with high importance for patient HRQoL. The objective of this study was to review, analyze, and understand trends in the PRO instruments used in patients with Glaucoma. **METHODS:** A systematic literature search for Glaucoma trials with PROs endpoints was undertaken for the databases Pubmed, Embase, Biosis, Google Scholar and Cochrane. Data was collected for the study size, interventions, year, PRO instrument and results for PROs. Analysis for conducted to identify trends in commonly used PRO instruments and categorize results as positive, neutral or negative. **RESULTS:** A total of 31 studies with a total of 9819 patients were identified. In these studies there were eleven different PROs instruments were identified that were Glaucoma health perception index, Glaucoma quality of life questionnaire (Glau-QoL), Glaucoma utility index, Impact of vision impairment, Low vision quality of life questionnaire, National eye institute visual function index-19 items, National eye institute visual function index-51 items, Nursing home vision quality of life questionnaire, Quality of life and visual function questionnaire, Vision core module 1, and Vision quality of life index. The most commonly used instruments were Impact of vision impairment (used in 7 studies) and Low vision quality of life questionnaire (used in 4 studies). **CONCLUSIONS:** Patients with glaucoma have significant impairment in their QoL, hence collection of such data is important for new medical products. PRO instruments such as Impact of vision impairment and Low vision quality of life questionnaire have been commonly used to generate evidence to show which therapies improve patient QoL.

#### PSS43 CORRELATIONS BETWEEN CHANGES IN THE URTICARIA ACTIVITY SCORE (UAS7) AND THE DERMATOLOGY LIFE QUALITY INDEX (DLQI) FROM BASELINE TO 28 OR 40 WEEKS: COMPARISONS OF TRAJECTORIES OF CHANGE IN PATIENTS WITH CHRONIC SPONTANEOUS/IDIOPATHIC URTICARIA (CSU/CIU)

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**OBJECTIVES:** The UAS7 is a patient-reported measure of urticaria symptoms. Daily pruritus scores and number of hives are summed over 7 days for a weekly score. The DLQI was developed as a brief (10-item) patient-reported measure with one-week recall for routine clinical use to assess the psychosocial effects of skin disease. The objective of this analysis was to examine changes in the UAS7 with those of the DLQI to see if the DLQI could be used in a clinic visit in lieu of collecting one week of UAS7 diary data. **METHODS:** Data come from three pivotal, phase 3 clinical trials investigating the effects of omalizumab for patients with refractory CSU/CIU (publication available elsewhere). DLQI data were collected at baseline and weeks 4, 12, 24, and 40 (ASTERIA I and GLACIAL), and baseline and weeks 4, 12, and 28 (ASTERIA II). UAS7 score was reported at baseline and every four weeks but data from the same weeks as the DLQI were used for these analyses. Pooled data from

all 3 studies were analysed using latent growth models to generate intercepts and slopes of change across trials for each patient, irrespective of treatment. Slopes of change were correlated to examine how closely DLQI changes mirrored UAS7 changes. **RESULTS:** Results indicated that both measures showed large improvements over the course of the trials: UAS7 and DLQI scores were high at the start of the study reflecting moderate-severe CSU/CIU (UAS7) and a very large effect on patient's life (DLQI). Correlations between changes in DLQI and changes in UAS7 by study end were 0.88, 0.85, and 0.88, indicating high correspondence between the two measures. **CONCLUSIONS:** These results suggest that collecting DLQI information in-clinic can provide an excellent indication of the weekly UAS7 score, and is more efficient for clinical practice routine in assessing CSU/CIU patients.

#### PSS44 ETANERCEPT PROVIDES IMPROVED QUALITY OF LIFE REGARDLESS OF THE PRESENCE OF PSORIATIC ARTHRITIS IN MODERATE/SEVERE PSORIASIS SUBJECTS FROM CENTRAL AND EASTERN EUROPE, LATIN AMERICA AND ASIA

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**OBJECTIVES:** Some psoriasis patients also have psoriatic arthritis (PsA), which increases disease burden and further reduces quality-of-life (QoL). Our objective was to compare QoL of subjects with both psoriasis and PsA to those with psoriasis alone, and to evaluate improvement on etanercept (ETN) therapy in specific countries of Central and Eastern Europe, Latin America, and Asia where data are limited. **METHODS:** Patients with moderate/severe psoriasis were randomized to 50mg ETN QW (once weekly) or 50mg ETN BIW (twice weekly, weeks 1-12), followed by 50mg QW (weeks 13-24). The following post-hoc assessments were included: EuroQoL-5D (EQ-5D); Dermatology Quality of Life Index (DLQI); Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue; Hospital Anxiety and Depression Scale (HADS); Medical Outcomes Study (MOS)-Sleep; and Work Productivity and Activity Impairment (WPAI). Subjects with and without PsA were pooled across ETN groups for comparisons of changes in scores from baseline to week 24, which were based on independent sample t-tests. **RESULTS:** Of 171 subjects analysed, 64 (37.4%) had PsA. Baseline demographic characteristics and QoL measures were similar in PsA and psoriasis-alone groups. EQ-5D scores improved significantly over time with ETN treatment in both subjects with and without PsA ( $P < 0.0001$ ) with similar adjusted mean improvement in both groups after 24 weeks (0.2 vs 0.2;  $P = 0.6202$ ). Improvement in EQ-5D greater than MID (change  $\geq 0.05$ ) at week 24 was observed in a greater proportion of PsA than psoriasis-alone subjects (74.6% vs 63.8%;  $P = 0.174$ ). Significant improvements from baseline in both PsA and psoriasis-alone groups were also observed after 24 weeks in DLQI (both  $P < 0.0001$ ), FACIT (both  $P < 0.01$ ) and HADS anxiety (both  $P < 0.0001$ ) scores. Improvements of other patient-reported outcomes were also observed at weeks 24 in both disease subgroups. **CONCLUSIONS:** ETN in both dose regimens provided significant improvement in QoL measures in subjects with moderate-to-severe psoriasis, regardless of the presence of PsA.

#### PSS45 QUALITY OF LIFE IMPROVEMENT WITH ETANERCEPT IN PATIENTS WITH MODERATE/SEVERE PSORIASIS FROM CENTRAL AND EASTERN EUROPE, LATIN AMERICA AND ASIA

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**OBJECTIVES:** To assess the impact of etanercept (ETN) on quality-of-life (QoL) through 24 weeks in patients with moderate/severe psoriasis in specific countries of Central and Eastern Europe, Latin America, and Asia where data are limited. **METHODS:** Patients with moderate/severe psoriasis were randomized to 50mg ETN QW (once weekly) or 50mg ETN BIW (twice weekly, weeks 1-12), followed by 50mg QW (weeks 13-24). Patients completed the Dermatology Life Quality Index (DLQI) EuroQoL 5D (EQ-5D), FACIT-Fatigue, HADS Anxiety Score, Psoriasis Subject Satisfaction Questionnaire, and Work Productivity Activity Impairment (WPAI) at baseline and subsequent visits. **RESULTS:** Of 171 patients analysed, 85 were randomised to ETN BIW and 86 to ETN 50 QW. Baseline DLQI scores were 14.8 in both treatment groups suggesting severe QoL impairment. Significant improvements in DLQI from baseline were observed at weeks 12 and 24 in both groups (all  $p < 0.0001$ ); mean improvement at week 12 for ETN BIW was greater than for ETN QW (10.8 vs 8.4,  $p = 0.001$ ), but was similar between groups at week 24 (11.0 vs 9.5,  $p = 0.063$ ). EQ-5D utility was significantly improved from baseline in both groups at weeks 12 and 24 (all  $p < 0.0001$ ), with mean improvement significantly greater for the higher dose at both time-points (week 12: 0.3 vs. 0.2,  $p = 0.029$ ; week 24: 0.3 vs. 0.2,  $p = 0.027$ ). Mean EQ-5D improvement at week 24 was greater than MID (change  $\geq 0.05$ ) in a significantly greater proportion of patients receiving BIW than QW (77.1% vs 58.8%;  $p = 0.013$ ). Improvements of other patient-reported outcomes from baseline were observed at weeks 12 and 24 in both treatment groups. **CONCLUSIONS:** At baseline, patients had severely impaired QoL, and improvement in QoL was achieved with both ETN regimens. Improvements observed with ETN BIW were significantly greater than with ETN QW for both DLQI and EQ-5D utility at week 12, but only for EQ-5D at week 24.

#### PSS46 QUALITY OF LIFE OF PATIENTS SUFFERING FROM EXUDATIVE AGE-RELATED MACULAR DEGENERATION AND TREATED BY INTRAVITREAL INJECTIONS AND ITS PREDICTORS: THE EQUADE STUDY

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