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FIRST REAL-WORLD STUDY ASSESSING HEALTH UTILITY VALUES FOR CHRONIC SPONTANEOUS/IDIOPATHIC URTICARIA USING THE EQ-5D

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OBJECTIVES: Although chronic spontaneous (idiopathic) urticaria (CSU/CIU) is not life threatening, it can significantly impact a patient's life when not adequately controlled by medication. Patients experience disturbing itch, intermittent pain, lack of sleep, occupational disabilities and social isolation with high impact on health-related quality of life (HRQoL). However, data on the humanistic burden associated with symptomatic persistent CSU/CIU is scarce. Here we present data on utility values from the first international burden of illness study in CSU/CIU. **METHODS:** ASSURE-CSU is an observational, non-interventional study which included a 1-year retrospective medical record abstraction and a cross-sectional patient-reported outcomes survey. Adult CSU/CIU patients aged >18 years with disease persisting for ≥12 months despite treatment were assessed. Utility values and domain scores from EQ-5D-3L were described for Canada, Germany, UK and the Netherlands. **RESULTS:** A total of 88, 98, 79 and 99 patients completed the patient survey which included the EQ-5D-3L in Canada, Germany, UK and the Netherlands, respectively. The mean (SD) EQ-5D-3L utility score was 0.71 (0.30) for Canada; 0.71 (0.25) for Germany; 0.72 (0.31) for UK and 0.76 (0.27) for the Netherlands. Among the different dimensions of EQ-5D-3L, pain/discomfort was the most affected with 62.0%, 70.5%, 61.5% and 56.6% of patients reporting moderate to extreme problems, respectively. The second most affected dimension was anxiety/depression for Canada, Germany and UK with 41.8%, 51.6% and 45.6% of patients reporting moderate to extreme problems, respectively. For the Netherlands, usual activities (44.4%) was the second most affected dimension. Impact across all dimensions increased with disease severity and correspondingly utility values decreased. **CONCLUSIONS:** This is the first real-world study to assess utility values in CSU/CIU using EQ-5D. Utility scores were similar among the countries and ranged from 0.71 to 0.76, suggesting that CSU/CIU have significant impact on the patients' health status. Pain/discomfort was the most affected dimension across countries.

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DISEASE BURDEN, OUTCOMES AND COSTS AMONG ADULTS ADMITTED TO HOSPITAL IN THE UNITED KINGDOM (UK) DUE TO PLAQUE OR ERYTHRODERMIC PSORIASIS

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OBJECTIVES: To evaluate disease burden, clinical and patient-reported outcomes and healthcare costs of patients admitted to hospital for management of plaque or erythrodermic psoriasis. **METHODS:** This observational study enrolled 61 eligible patients from 107 hospital stays across 9 UK hospitals. Sites recorded Psoriasis Area Severity Index (PASI) at admission and discharge, psoriasis treatments, and length of stay (LOS). Patients reported psoriasis-related symptoms, health status (SF-12v2, EQ-5D-3L), mood (HADS), productivity (WPAI), and dermatology-related quality of life (DLQI) at admission, and also reported psoriasis-related symptoms, EQ-5D-3L, and DLQI at discharge. An algorithm assigned cost/hospital stay. Descriptive statistics are based on those responding to each item. Statistical significance evaluated at the 0.05 level. **RESULTS:** Mean age was 45.5 years; 50.8% were male. Mean time since psoriasis diagnosis was 20.0 years. Most (78.7%) had ≥1 previous psoriasis-related hospitalization. Mean number of physician-diagnosed co-morbid conditions was 2.5. At admission, mean SF-12v2 Physical and Mental component summary scores were 35.4 and 32.1, respectively; mean HADS scores were 9.7 (anxiety) and 9.6 (depression) indicating substantial impairment. Forty-five percent reported changing job, role, or position at work due to psoriasis. Mean WPAI activity impairment at admission was 68.7%; among the 35.1% employed for pay, mean WPAI work impairment was 79.2%. Mean PASI improved from admission to discharge (25.2→12.1; p<0.0001). Also, improvement was seen at discharge for EQ-5D-3L (0.34→0.60), DLQI total score (20.1→12.0), and psoriasis symptom scores (all p<0.05). Mean (range) LOS was 17.0 (2.71) days; for 8 patients achieving a 75% reduction in PASI (PASI75), mean LOS was 18.1 vs. 13.1 days for 27 patients not achieving PASI75 (p=0.11). Mean (SD) cost/hospital stay was £4,875 (±£3,096). **CONCLUSIONS:** Disease burden, LOS and cost are substantial among patients hospitalized for psoriasis. On average, patients improved during their hospital stay. Nonetheless, they reported suboptimal clinical and patient-reported outcomes at discharge.

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EVALUATION OF PSORIASIS PATIENTS' ATTITUDE TO RISK: BENEFIT AND THERAPEUTIC TRADEOFFS IN THEIR CHOICE OF TREATMENTS

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OBJECTIVES: Treatment options continue to emerge for managing psoriasis, with different risk/benefit profiles and routes of administration. This study was designed to elicit UK patients' relative strength of preference regarding treatment effectiveness, risks of side effects, and mode/frequency of administration. **METHODS:** A stated preference survey (using a discrete choice experiment [DCE]) was designed to present participants with hypothetical treatment choices. Treatments were described in terms of reducing the body surface area (BSA) affected by psoriasis, mode of administration, increase in risk of diarrhea or nausea in the short-term, and 10-year risk of melanoma, tuberculosis, or serious infection (e.g., pneumonia). Standard DCE Methods with an orthogonal design were used; the survey was pilot-tested in 6 participants. **RESULTS:** Psoriasis patients (n=292; mean age=48.5 years; mean BSA=9.3%; mean Dermatology Life Quality Index=10.5; 25.7% with prior biologic experience and 34.9% with psoriatic arthritis) were recruited in the UK. Participants strongly preferred to avoid increasing their risk of melanoma (odds ratio [OR]=0.44/5% increased 10-year risk), tuberculosis, and serious infections (OR=0.73/5% increased 10-year risk for both) and preferred twice-daily tablets to weekly injections (OR=0.74) or injections every 2 weeks (OR=0.86). Participants preferred to avoid treatments with a risk of diarrhea or nausea in the first few weeks after initiation (OR=0.87/5% increase) and preferred treatments that effectively resolve plaque lesions (OR=0.93 for each hand palm area still affected). All ORs were statistically significant. Biologic-naïve participants were more likely to prefer oral tablets to injections and were less risk-tolerant for serious adverse events. **CONCLUSIONS:** All attributes of treatment considered were found to be significant predictors of choice. Patients showed strong preferences for avoiding treatments with risk of serious toxicities and avoiding injectable therapy, and a lower preference for treatments with greater efficacy. These preferences were consistently stronger in biologic-naïve patients.

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ASSESSMENT OF DENTAL STATUS AND PERCEPTION TOWARDS ORAL HEALTH AMONG PHARMACY STUDENTS IN QUETTA, PAKISTAN

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OBJECTIVES: This study is design to assess the dental status and perception towards oral health among pharmacy students. **METHODS:** The study is questionnaire bases cross sectional study. Study is conducted in Faculty of Pharmacy, University of Balochistan, Quetta by using convenient sampling. The descriptive statistics was used to present the demographic and disease related information. Inferential statistics was used to the evaluation relationship among study variables. All analyses were performed using SPSS 20.0. **RESULTS:** Out of 197 participants 196 (66.0%) were male. Majority of participants 267 (89.9%) having age ranges between 18-24 years. One hundred ninety one (64.3%) describe that they have no problem in chewing and 172 (53.9%) are satisfied with their teeth appearance which shows the satisfaction of participants concerning their oral dental health. Majority of respondents 120 (40.4%) were satisfied with their teeth. One hundred and sixty one (54.2%) respondents were having minor teeth problems. Score for self-rating of dental health in majority of participants 121 (40.7%) was excellent. When discussing the self-rating score no significance difference was found in participants having dental problem, broken filling, broken tooth, cavities, bleeding gums, bad breath, stained teeth, aches and broken denture. **CONCLUSIONS:** Present Study concluded that although the participant were satisfied with their oral dental health, yet they are not aware about the proper hygiene and oral dental health. Awareness program must be initiated for students, focusing primarily on dental/oral health.

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CHARACTERISTICS OF ACNE VULGARIS IN EUROPEAN ADOLESCENTS AND PATIENTS PERCEPTIONS

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OBJECTIVES: Acne vulgaris is one of the most common skin conditions, affecting primarily the adolescents. The psychological impact associated with the condition could be explained by the predominance of lesions in the face. The objective of the present study was to describe the characteristics of the disease and its management in Europe considering the patients' perspective. **METHODS:** A cross-sectional survey was conducted in a sample of individuals residing in Europe and aged 15 to 24. To ensure representativeness, the quota method was applied considering age, sex, residence location and occupational status of the reference person. Study participants were asked to complete an online questionnaire specifically developed for the study and Results were analysed descriptively. **RESULTS:** A total of 3099 study participants declared currently having acne. Outside of the face, the back was affected by lesions in 61.05% of individuals on average (65.95% of men and 56.22% of women). Most patients (27.03%) reported their general physician or dermatologist as the main source of information on acne. However, advices were also often sought from relatives and internet. In addition, whereas the diagnosis of acne is generally made by a dermatologist (29.69%), most patients, reporting acne in our study, declared that no medical diagnosis was ever made (39.3%). This can explain why most individuals (28.65%) reported using anti-acne cosmetics advised by their pharmacists instead of prescribed treatments. Finally, according to patients' perspective, acne is generally considered a minor issue however, for 21.3% of individuals it represents a major problem and 1.9% lives it as a real burden. These Results are consistent across the selected European countries. **CONCLUSIONS:** Acne is a common disease considered a minor issue by most adolescent patients and commonly self-managed using anti-acne cosmetics. However, patients often sought information and advices from healthcare professionals such as general practitioners, dermatologists or pharmacists.

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IMPACT OF ALEXITHYmia AND DISEASE CHARACTERISTICS ON WORK PRODUCTIVITY AND ACTIVITY IN PSORIASIS PATIENTS WITH SHORT DISEASE DURATION: EPIDEPSO MULTICENTRE STUDY

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OBJECTIVES: Alexithymia is the inability to describe and project emotions in the self. Our objective was to assess the association between alexithymia in psoriasis (PSO) and loss of work productivity and activity in PSO patients. **METHODS:** EPIDEPSCO (NCT01964443) is a 12-month observational, international study, to investigate alexithymia and other psychosocial comorbidities in PSO with disease duration ≤ 10 years. Presence of alexithymia was defined as a score of ≥ 61 on the 20-item Toronto Alexithymia Scale. Work productivity and activity were assessed using the Work Productivity and Activity Impairment Questionnaire: PSO (WPAI-PSO). Clinical assessments and patient-reported outcomes included the Psoriasis Area and Severity Index (PASI) and the Dermatology Life Quality Index (DLQI). **RESULTS:** The data displayed are from baseline analyses. The prevalence of alexithymia was 39% (95% CI 35–43%). Alexithymic patients had higher unemployment rates than non-alexithymic patients (48% vs 25%, $p < 0.0001$). WPAI-PSO Results among employed patients showed comparable absenteeism between alexithymic and non-alexithymic patients, but more impairment at work (presenteeism) (29% vs 13%) and productivity loss (34% vs 17%) was greater in alexithymic than non-alexithymic patients. In both employed and unemployed patients there was greater activity impairment among alexithymic patients (38% vs 20%, all $p < 0.0001$). In the overall population, patients with a PASI score > 10 showed more impairment at work (24% vs 15%), greater productivity loss (30% vs 18%) and greater activity impairment (36% vs 20%) than those with a PASI score ≤ 10 (all $p < 0.01$). Moderate correlations between DLQI and presenteeism ($r = 0.56$), productivity loss ($r = 0.55$) and activity impairment ($r = 0.65$, all p -values < 0.0001) were identified. **CONCLUSIONS:** In PSO patients, the inability to describe and project emotions may have an impact on daily work productivity and activity. Our data indicate that there is a complex relationship between alexithymia, disease severity, and quality of life upon employment status and productivity.

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VALIDATION OF THE SPANISH VERSION OF THE URTICARIA ACTIVITY SCORE (UAS) AND ITS USE OVER ONE WEEK (UAS7)

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OBJECTIVES: To validate the Spanish version of the UAS, the most widely used patient-reported outcome measure for patients with chronic idiopathic urticaria (CIU), and its administration over 7 consecutive days (UAS7). **METHODS:** Observational, prospective, multicentre study in adult patients with CIU. The UAS has 2 items (intensity of pruritus and number of hives, scored 0-3) and ranges from 0-6 (lowest to highest disease activity). The UAS7 is the sum of UAS over 7 consecutive days. Both scales were completed at baseline and after 6 weeks, together with health-related quality of life (CU-Q2oL and EQ-5D) and disease severity (Clinician (CRS) and Patient Rating Scale (PRS); Clinician (CRSC) and Patient Rating Scale of Change (PRSC)) questionnaires. **RESULTS:** 166 patients were included. Overall, $< 16\%$ of responses were missing or non-valid. Maximum floor and ceiling effects were 19.3% and 6.0%, respectively. Internal consistency was good (Cronbach's alpha: UAS=0.68 [baseline] and 0.83 [6 weeks]; UAS7=0.83 in both visits) and test-retest reliability was adequate (intraclass correlation coefficients of 0.65 (UAS) and 0.84 (UAS7) in stable patients ($n=37$ and 49, respectively)). Known-groups validity was supported by significantly different scores between severity subgroups according to CRS and PRS ($P < 0.001$ in all cases). Good construct validity was also observed, with moderate/strong correlations with the CU-Q2oL scores ($r=0.37-0.59$), and weak correlations with the EQ-5D visual analogue scale ($r=-0.15$ to -0.30) and index ($r=-0.15$ to -0.28). Sensitivity to change was good, with large effect sizes (≥ 0.8) for patients with ≥ 3 points-change in severity (CRSC or PRSC). The minimally important difference for the UAS7 ranged from 4-5, less than reported for the English version (9.5-10.5). **CONCLUSIONS:** The Spanish versions of UAS and UAS7 scales are valid, applicable and reliable tools to assess disease control in the clinical practice in patients with CIU. A 4-5 point change on the Spanish UAS7 might be interpreted as an important difference.

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SOCIAL IMPACT OF PSORIASIS IN SPAIN: A RASCH ANALYSIS FROM A SURVEY

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OBJECTIVES: Psoriasis is a chronic skin disease that causes an important physical, psychological, and economic impact on the people affected. However social impact has not been studied until recently. The objective of this study was to examine the social impact of psoriasis as reported by patients. **METHODS:** Data came from the study "Acción 2014", an online survey carried out by the Spanish association of patients and their families affected by Psoriasis and psoriatic arthritis ("Acción Psoriasis"), the study took place from December 2013 to April 2014. We included all psoriatic Spanish participants, and we examined the set of 13 items referred to the social impact of psoriasis using a Rasch model. This implied studying the scale functioning, item fit, item dependency, and the unidimensionality assumption. The units of the Rasch (logits) were transformed into a 0-10 scale. We analysed overall differences between groups of patients with ANOVA tests. **RESULTS:** A

total of 731 participants had the inclusion criteria, mean age was 45 years old (SD=6.3). Seventy six percent ($n=490$) reported being affected of a skin psoriasis, 1.64% ($n=12$) by psoriatic arthritis, and 31.33% ($n=229$) by both types. Items causing higher social impact were those related to personal exposure in public places (scale 0-10: 6.08) and participation in sport activities (scale 0-10: 5.68); Less than half of participants reported managing these two issues successfully. Social impact of psoriasis was higher in younger participants, living alone, or not married, unemployed, and with less household income ($p < 0.001$). **CONCLUSIONS:** Impact of psoriasis might be assessed and requires clinical, social actions and emotional support to ensure patients with psoriasis having the best care. Specific population groups need specific health care interventions to avoid harms of socialization linked to psoriasis.

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IMPROVED VISUAL FUNCTION IS ASSOCIATED WITH INFLAMMATION REDUCTION IN SUBJECTS WITH NON-INFECTIOUS UVEITIS (NIU) OF THE POSTERIOR SEGMENT TREATED WITH INTRAVITREAL SIROLIMUS: RESULTS FROM SAKURA STUDY 1

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OBJECTIVES: To examine the association between inflammation reduction and visual function response in subjects with active NIU of the posterior segment who received intravitreal sirolimus in SAKURA Study 1, a phase 3, double-masked, multinational study. **METHODS:** Visual function was assessed via best corrected visual acuity (BCVA) and the National Eye Institute Visual Function Questionnaire (NEI-VFQ-25). Principal component analysis was used to identify 3 visual function measures. Minimal clinically important differences (MCID) for the VFQ-25 Composite and VFQ-25 Mental Health subscale scores were established based on the standard error of measurements of baseline scores. For BCVA, 2 ETDRS lines of improvement was used as a meaningful threshold. Response on any single measure was considered an overall visual function response. Anatomic vitreous haze (VH) response was defined as a VH score of 0 or 0.5+ at Month 5. **RESULTS:** 347 subjects were randomized 1:1:1 to every-other-month injections of intravitreal sirolimus 44 μg (active control), 440 μg , or 880 μg . Significantly more subjects in the 440 μg group (52.6%) achieved an anatomic response compared with the 44 μg group (35.0%) ($p = .008$). When the MCID for the NEI-VFQ-25 Composite and Mental Health subscale scores were established at 4.3 and 11.7 points, respectively, the association between anatomic and visual function response was statistically significant. In those achieving an anatomic response, a significant relationship was seen with all visual function response measures: VFQ-25 Composite score (OR=2.234; $p = .0004$); VFQ-25 Mental Health subscale score (OR=2.837; $p < .0001$); BCVA 2-line improvement (OR=2.601; $p = .0009$), and overall visual function response (OR=2.650; $p < .0001$). **CONCLUSIONS:** In SAKURA Study 1, the reduction of inflammation to a VH score of 0 or 0.5+ was significantly associated with improved visual function as measured by BCVA, VFQ-25 Composite, VFQ-25 Mental Health, and overall visual function responses. Thus, achieving a VH response of 0 or 0.5+ can be considered a patient-relevant outcome.

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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:** 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.

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BURDEN OF INFANTILE HEMANGIOMA ON FAMILY: AN INTERNATIONAL CROSS-SECTIONAL STUDY

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OBJECTIVES: Infantile hemangioma (IH) is a benign neoplasm, resulting from vascular proliferation, with an estimated incidence of 3 to 10% within the first year of birth. While, in most cases, IH involute spontaneously by the age of 7 years, some hemangiomas (i.e. life or function-threatening IH, risk of