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DIFFERENT PERCEPTIONS OF QUALITY OF LIFE AMONG PSORIASIS PATIENTS AND THEIR TREATING PHYSICIANS

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OBJECTIVES: The aim of this study was to review whether there is a mismatch between how both physicians and patients perceive their quality of life and how this is perceived by their treating physicians. METHODS: A cross-sectional survey of Rheumatologists/Dermatologists (n = 134) and patients consulting with the Psoriasis Area Severity Index (PASI) at the United States June/September 2013. Each specialist completed a comprehensive record form on patients consulting for their psoriasis. Patients were invited to complete a questionnaire and also the EQ-5D-5L instrument. Physicians completed the same instrument for how they envision the status of that same patient. Patients were split into 3 equal groups based on their health utility scores. RESULTS: No significant correlation was found between the patient- and physician-reported health utility scores (Pearson correlation coefficient = 0.48, P > 0.05). In 34% of the cases there was a significant (physicians scored the patients worse than the patients scored themselves) and 14 % was an underestimation (patients scored physicians worse than they were). Of 352 self-reported patients, 44% of cases revealed a mismatch between physician and the patients point of view. Out of that 34%, 20% was an overestimation (physicians scored the patients worse than the patients scored themselves) and 14 % was an underestimation (patients scored physicians worse than they were). Of 352 self-reported patients, 44% of cases revealed a mismatch between physician and the patients point of view. The Reliability of the Patient Reported Scal Evaluation Questionnaire (PR-SEQ) in a Cohort of Adults with Linear SCARS

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OBJECTIVES: To test the reliability of the Patient Reported Scal Evaluation Questionnaire (PR-SEQ) in a general scal population at two time points and in two formats: self-scoring and electronic. METHODS: The PR-SEQ is a measure of scar experience, was administered to a total of 512 clinic- and self-recruited subjects with qualifying scars. The 101 clinic-recruited subjects were administered the PR-SEQ in a pen/paper format at Baseline and at 3 Timepoint 1 (T1) and Timepoint 2 (T2). The internal consistency reliability was assessed using Cronbach’s alpha for the total T1 cohort (n=121), test-retest reliability was assessed using the intraclass correlation coefficient (ICC) based on an ANOVA model for the T1-T2 retest cohort (n=359), and between forms reliability was assessed using the ICC for the clinic cohort data from baseline and T1 (n=100). RESULTS: Cronbach’s alpha was 0.96 for the PR-SEQ total score and 0.88 for Appearance (n=5 items), 0.68 for Symmetry (3 items), 0.92 for Both (8 items), and 0.95 for Impact (14 items) domains. The ICC for the test-retest cohort was 0.85 for the total score and 0.76, 0.78, 0.80, and 0.81 for the domains of Appearance, Symmetry, and Both, respectively. Between forms reliability was acceptably acceptable with scores of 0.84, 0.90, 0.92, and 0.95 for the domains, and 0.94 for the total score. CONCLUSIONS: Overall, the two versions of the PR-SEQ demonstrated acceptable reliability for the domains and temporal stability with the exception of the internal consistency of the 3-item Symptom domain. Future item reduction may be possible without significant risk to the reliability of the instrument.

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QUALITY OF LIFE IN PATIENTS SUFFERING FROM PSORIASIS VULGARIS USING EQ5D: A SYSTEMATIC LITERATURE REVIEW

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OBJECTIVES: There is a paucity of evidence regarding a well-defined, reliable, and valid method for measuring efficacy outcomes in acute bacterial skin and skin structure infection (ABSSSI) trials. Evidence suggests a relationship between a decrease in lesion size and patient-centered outcomes related to pain, however, there is no patient reported outcome (PRO) to capture additional symptoms which patients experience in this study. The purpose of this study was to develop a PROM for skin infection as reported by patients, and comprehensively capture these symptoms. METHODS: One-on-one telephone interviews were conducted with patients diagnosed and treated in the past 4-7 days in the United States. ABSSSI patients with a wound infection, cellulitis (including erysipelas), or major abscesses were included. Patients were asked to describe their skin infection and how it may have affected their life. The data was continually analyzed using an iterative process to identify themes and domains which were developed into a new PRO instrument to assess patient-reported ABSSSI symptoms. Saturation was monitored according to the FDA PRO guidance. RESULTS: Thirty-four patients participated in concept elicitation interviews from four sites: Thirteen patients were diagnosed with major abscesses, twelve with wound infection, and nine with cellulitis. Mean age of the sample was 39 years (SD = 12.2); 35% were female. The main themes to emerge included signs (e.g., growth, color), symptoms (e.g., soreness), and impacts on functionality (e.g., social, physical) related to the skin infection. The most commonly reported symptoms included experiencing pain (n=32), swelling (n=31), and drainage or leakage at the site of the infection (n=27). CONCLUSIONS: Qualitative data gathered in the initial concept elicitation interviews will be combined with input from experts to form the basis of a new PRO instrument to assess patient-reported ABSSSI symptoms. This study will also ensure that the newly developed PRO instrument has established qualitative content validity for the types of ABSSSI patients being interviewed.

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PSYCHOEMOTIONAL EVALUATION OF THE PSORIASIS SYMPTOM DIARY USING PHASE 3 TRIALS

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OBJECTIVES: To evaluate reliability, validity, and responsiveness of the Psoriasis Symptom Diary (PaD) using data from patients with moderate-to-severe chronic plaque-type psoriasis. METHODS: Analyses were completed using pooled data from the screening (1-4 weeks) and induction (12 weeks) periods of two randomized, double-blind, double-dummy, placebo-controlled, multicenter phase 3 trials (N = 820, CAIN457A230 and CAIN457A2303) designed to assess the safety and efficacy of secukinumab. Patients aged 18+ years were randomized 1:1:1:1:1 in CAIN457A230 to subcutaneous treat groups (secukinumab 150 mg, secukinumab 300 mg, placebo); and 1:1:1:1 in CAIN457A2303 including an etanercept 50 mg (twice per week; PaD) or control (every 48-hour interval; control)). The PaD is a visual analog scale electronically administered every evening. Intra-class correlations were calculated to estimate test-retest reliability. Construct validity hypotheses were based on correlations with the Psoriasis Area and Severity Index (PASI), Investigator’s Global Assessment (IGA), Patient Global Impression of Change (PGIC), the Dermatology Life Quality Index (DLQI), and the EuroQol 5-Dimension Health Status Questionnaire (EQ-5D). Mean differences between known groups and responsiveness effect sizes were computed. Phase 2 derived anchor-based PGIC thresholds and cumulative distribution function (CDF) plots were used to describe meaningful change. RESULTS: The PaD items yielded high intraclass coefficients (> 0.90). Correlations were in the anticipated direction and by week 12 were moderate to strong (0.41 to 0.73) in magnitude, demonstrating construct validity. Item-level means differed predictably and significantly across known groups based on the PASI and IGA. Responsiveness effect size estimates were moderate to large (≥ 0.5 to ≥ 1.4). CDF plots show that the percentage of responders was consistently higher in the treatment arms than placebo across the range of change scores. CONCLUSIONS: Results support the reliability, validity, and responsiveness of the PaD and its use as a tool to enhance treatment decisions in patients with moderate-to-severe plaque psoriasis.