THROUGH CONCEPT ELICITATION INTERVIEWS IN CHRONIC LOW BACK PAIN

OBJECTIVES: The primary objective was to examine the effect of 8% capsaicin patch on change in "usual pain" using a PNRs (Pain Numeric Rating Scale) from baseline to end of treatment. A secondary objective was to examine utility scores assessed by the EQ-SD.

METHODS: Adult patients (n=213) diagnosed with peripheral neuropathic pain (excluding diabetes polyneuropathy) were included. The following parameters were investigated over a 12 week follow up period after a single treatment: usual pain intensity over the last 24 hours, i.e., usual pain - EQ-SD - Size of treated area. RESULTS: A total of 196 patients completed the study, 66 women and 34 men. Mean age was 54.2 years (range 18-87). At baseline, the "usual pain" intensity was 6.3 (SD 1.8). The mean change of PNRs from baseline to 14 - 90 days post treatment (average pain reduction) was -0.90 (SD 2.08), p = 0.001. Maximum mean reduction of "usual pain" within the first 14 days was -1.16 (SD 2.7). Mean EQ-SD health status was 0.29 (SD 0.31) at baseline (range -0.38-1.00). During the post-treatment period the change was 0.26 (SD 0.30), p < 0.001. At baseline, 66% of all patients reported specific impacts of pain in the domains of comfort and corresponding figures for the post-treatment period was 43%. Median area treated was estimated to 179 cm² (range 3-1120) corresponding to 1.3 patches used per patient per treatment.

CONCLUSIONS: In this population of patients with peripheral neuropathic pain and a markedly reduced PNRs, a single treatment of capsaicin 8% significantly reduced patients' experience of "usual pain" and improved short-term QoL evaluated by EQ-SD.

PSY37 PATIENT-REPORTED OUTCOME (PRO) ASSESSMENTS IN SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)

OBJECTIVES: The objective was to evaluate the reliability and validity of the LIT, a 10-item PRO assessment of the impact of SLE on the patient’s life.

METHODS: Baseline data were collected on 325 SLE patients during a clinic visit. Patients completed the LIT, SF-36v2, LupusQoL, and PHQ-9. Both patients and physicians completed a questionnaire on the feasibility/acceptability of LIT. Patients completed the LIT 7-14 days following baseline to assess test-retest reliability. Psychometric properties (Construct validity, Impact scores, and SLECC/ACR Damage Index) were assessed.

RESULTS: 281 patients (24 female) completed the LIT. A1, 91.0% of LIT items were considered relevant by patients and physicians. Construct validity was evaluated by correlating LIT scores with scale scores from the SF-36v2, LupusQol, and PHQ-9. Mean LIT scores differed between patients that differed in PGA ratings and presence/absence of a recent flare. ANOVA and Student’s t-test were used to test mean differences in LIT scores across patient groups. It was hypothesized that LIT scores would be lower among patients with lower SLE-CRP.

CONCLUSIONS: The LIT is a reliable and valid instrument for assessing the impact of SLE on patient’s functioning and well-being.

PSY40 VALIDATION OF THE LUPUS IMPACT TRACKER (LIT), A PATIENT-REPORTED OUTCOME (PRO) TOOL, IN A PROSPECTIVE MULTICENTER LONGITUDINAL STUDY OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) PATIENTS

OBJECTIVES: Evaluate the reliability and validity of the LIT, a 10-item PRO assessment of the impact of SLE on the patient’s life. Additionally, the acceptability and feasibility of LIT from the patient’s and physician’s perspectives was assessed.

METHODS: Baseline data were collected on 325 SLE patients during a clinic visit. Patients completed the LIT, SF-36v2, LupusQoL, and PHQ-9. Both patients and physicians completed a questionnaire on the feasibility/acceptability of LIT. Patients completed the LIT 7-14 days following baseline to assess test-retest reliability. Psychometric properties (Construct validity, Impact scores, and SLECC/ACR Damage Index) were assessed.

RESULTS: 281 patients (24 female) completed the LIT. A1, 91.0% of LIT items were considered relevant by patients and physicians. Construct validity was evaluated by correlating LIT scores with scale scores from the SF-36v2, LupusQol, and PHQ-9. Mean LIT scores differed between patients that differed in PGA ratings and presence/absence of a recent flare. ANOVA and Student’s t-test were used to test mean differences in LIT scores across patient groups. It was hypothesized that LIT scores would be lower among patients with lower SLE-CRP.

CONCLUSIONS: The LIT is a reliable and valid instrument for assessing the impact of SLE on patient’s functioning and well-being.

PSY38 SPONTANEOUS AND PROBED DISEASE-DEFINING CONCEPTS IDENTIFIED THROUGH CONCEPT ELICITATION INTERVIEWS IN CHRONIC LOW BACK PAIN

OBJECTIVES: To identify symptoms and impacts associated with chronic low back pain (CLBP) that patients report spontaneously and in response to probes during clinical elicitation interviews.

METHODS: Adult patients (18-80 years) with clinical diagnosis of clBP of non-malignant origin present for at least 3 months with a current pain score ≥4 on the Numeric Rating Scale (N0-10). This study was conducted at U.S. and Germany sites. In order to explore relevance of concepts to patients, trained qualitative interviewers conducted semi-structured individual interviews, using open-ended questions to elicit spontaneous reports of symptoms/impact/concepts, followed by probe questions to ensure full coverage of concept domains. Transcripts were coded using Atlas ti and summarized by distinct concepts. Interview guide notations were used to tag each concept offered by spontaneous versus probed report. RESULTS: Forty-three patient interviews were conducted (mean age 54 ± 13.0, 53.5% female, 46.4% White/Caucasians). Mean (SD) pain NRS for U.S. and Germany sites was 6.7 (±1.3). Spontaneously reported symptoms included: Numbness (51.2% of subjects), Burning (39.5%), and Pain that was Shooting (37.2%), Stabbing (37.2%), and Sharp (37.2%). The low back pain symptoms reported most often in response to probes were: Reduced Mobility (55.8%), Fatigue (46.5%), Emotional Impacts (48.8%). Impacts reported most often in response to probes included Low Energy because of pain (67.4%), Productivity (61.5%), Financial Impact (46.5%), Driving (39.5%), and Relationships (37.2%). CONCLUSIONS: Given the variety of symptoms and impacts described by patients as part of their CLBP experience, those reported spontaneously may be more relevant to patients compared to those probed. The feasibility/probability of using LIT probed and spontaneous may be useful in increasing the overall sensitivity of the patient-reported outcome assessment tool to detect change.

PSY39 VALIDATION OF THE LUPUS IMPACT TRACKER (LIT), A PATIENT-REPORTED OUTCOME (PRO) TOOL, IN A PROSPECTIVE MULTICENTER LONGITUDINAL STUDY OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) PATIENTS

OBJECTIVES: To develop a reliable and valid instrument for assessing the impact of SLE on patient’s functional and well-being.

METHODS: SLE patients (n=213) diagnosed with peripheral neuropathic pain were included. The following parameters were investigated over a 12 week follow up period after a single treatment: usual pain intensity over the last 24 hours, i.e., usual pain - EQ-SD - Size of treated area. RESULTS: A total of 196 patients completed the study, 66 women and 34 men. Mean age was 54.2 years (range 18-87). At baseline, the "usual pain" intensity was 6.3 (SD 1.8). The mean change of PNRs from baseline to 14 - 90 days post treatment (average pain reduction) was -0.90 (SD 2.08), p = 0.001. Maximum mean reduction of "usual pain" within the first 14 days was -1.16 (SD 2.7). Mean EQ-SD health status was 0.29 (SD 0.31) at baseline (range -0.38-1.00). During the post-treatment period the change was 0.26 (SD 0.30), p < 0.001. At baseline, 66% of all patients reported specific impacts of pain in the domains of comfort and corresponding figures for the post-treatment period was 43%. Median area treated was estimated to 179 cm² (range 3-1120) corresponding to 1.3 patches used per patient per treatment.

CONCLUSIONS: In this population of patients with peripheral neuropathic pain and a markedly reduced PNRs, a single treatment of capsaicin 8% significantly reduced patients' experience of "usual pain" and improved short-term QoL evaluated by EQ-SD.
ceived preventive treatment; 60.4% were on-demand treatment. Severe HB adults reported significantly poorer HRQoL than the moderate subgroup mainly on physical components. No HRQoL difference was observed among children. The average annual direct cost was €95,619 (SD 83,142) with no significant difference between adults and children, but with a difference with severity status (3.3 times higher in severe vs. moderate HB, p < 0.001). Subsitutive therapy represented 90%, of the total health care cost of HB patients (65%). Even if the prophylaxis strategy lead to higher costs than the on-demand strategy (p < 0.001), it allows avoiding haemor-
phagic events and remains in acceptable cost-effectiveness range. **CONCLUSIONS:** To date, no economic burden of disease studies focusing only on HB have been published. The OQOL study provides an important source of economic informa-
tion for health care payers.

**OBJECTIVES:** To describe pain medication use in patients with chronic lower back pain (CLBP) after initiating duloxetine or standard of care (SOC) for pain management. **METHODS:** Pharmacy and medical claims from SDI Health were analyzed for adult patients with CLBP who initiated duloxetine (SSRI/GNOM/MUSCLE relaxants, gabapentin, pregabalin, venlafaxine, and tricyclic antidepressants) be-
 tween 11/2010 and 4/2011. Treatment initiation was defined as no pill coverage for duloxetine or SOC in previous 90 day. Included patients had no opioid use in 90 days before initiation. Propensity score matching was used to select patients with similar baseline demographic and clinical characteristics for duloxetine and SOC cohorts. Compliance to index medication was assessed via medication possession ratio (MPR) and proportion of days covered (PDC) for 6 months after initiation. Proportion receiving opioids and days on opioids after index date were assessed and regression models were estimated to compare opioid use between cohorts.

**RESULTS:** 766 patients initiated duloxetine and 6,206 patients initiated SOC. After matching, 743 patients were selected for the duloxetine (mean age: 57; fe-
male: 74%) and SOC (mean age: 57; female: 75%) cohorts, respectively. 92% of duloxetine cohort started on or below recommended dose (≤60mg). Dulox-
etine cohort had significantly higher MPR (0.78 vs 0.60) and PDC (0.50 vs 0.31), were less likely to use opioids (45% vs 61%), and had fewer days on opioids (mean: 18 vs. 25) than SOC cohort (all p < 0.001). After adjusting for demographic and clinical characteristics, duloxetine cohort used opioids less (OR: 0.76, 95% confidence interval: 0.65-0.88), and had fewer days on opioids (-6.9, 95% CI: -9.0 to -4.7, p < 0.001). **CONCLUSIONS:** CLBP patients initiating duloxetine had better compli-
cance to initiated medication and were less likely to use opioids than those initiating SOC.

**PSY44**

**A COST EFFECTIVENESS MODEL FOR THE MYCOPLASMAL DISEASE IN GREECE. AZACITIDINE VERSUS CONVENTIONAL CARE REGIMENS**

** objectives:** To evaluate the cost effectiveness of azacitidine treatment in com-
parison with Conventional Care Regimens (CCR), available in Greece. The analysis is based on a National Health Service perspective. **METHODS:** A Markov model was explored based on the Phase III randomized trial AZA-001, where patients were analyzed over their lifetime. The health outcomes were estimated on i) life years (LY) gained and ii) Quality Adjusted Life Years (QALYs) gained. The cost outcomes were the average direct costs associated with each MDS treatment arm (relating to drugs and medications, monitoring, routine follow-up and adverse event manage-
ment). The cost effectiveness of azacitidine treatment, compared to BSC, LDC, and SDC treatments, was based on the Incremental Cost Effectiveness Ratio (ICER). The model was personalized into the Greek Health Care System by launching a struc-
tured questionnaire addressed to Greek hematologists from 6 Hospitals. They pro-
vide information on the resource use for the management of blood product trans-
fusions and adverse events complications in Greece. **RESULTS:** The incremental cost of azacitidine compared to BSC was €59,708 and €27,074 respectively. With regard to QALYs azacitidine is also effective in reducing PASI (34.4%) and DLQI (27.0%) scores and reduction in PASI was moderately positively correlated with absenteeism, work productivity and activity impairment. Anti-TNF agents is also capable of quantifying the socio-economic burden and Health-Related Quality of Life (HRQOL) for patients with rare diseases (RD) and their caregivers in Europe. **OBJECTIVES:** To compare the economic burden and health-related quality of life in patients with rare diseases in Europe (BuroQol-RD project). **Spanish results**

**Limerová R, López-Bastida J, Serrano-Aguilar P, Posada-de-la-Paz M**

**FUNDAMENTO CANARIA DE INVESTIGACIÓN Y SALUD (FUCANIS), Las Palmas de Gran Canaria, Spain, Universidad de Castilla - La Mancha, Talavera de la Reina, Toledo, Spain, Canaries Health Service, Santa Cruz de Tenerife, Canary Islands, Spain, Instituto de Salud Carlos III, Madrid, Spain.**

**OBJECTIVES:** The BuroQol-RD project is intended to develop a disease based model capable of quantifying the socio-economic burden and Health-Related Quality of Life (HRQOL) for patients with rare diseases (RD) and their caregivers in Europe. Preliminary results from Spain are presented here. **METHODS:** On-line survey of patients and caregivers affected by Cystic Fibrosis, Prader-Willi Syndrome, Haemol-
ophilia, Duchenne Muscular Dystrophy, Epidermolysis Bullosa, Fragile X Syndrome, Scleroderma, Mucopolysaccharidosis, Juvenile Idiopathic Arthritis or Histiocytosis was launched in Spain through national patients organizations in September 2011.