SPONTANEOUS AND PROBED DISEASE-DEFINING CONCEPTS IDENTIFIED

minimize questionnaire burden. The practicality of these PRO instruments for use versions of validated PROs (e.g., SF-12, LIT) or instruments such as RAPID3 may varying degree of questionnaire burden and specificity to SLE symptoms. Shorter LupusPRO are the most widely used validated PRO instruments, but these have a items) are also being studied in SLE.

11 assessed general QoL and the rest assessed select (diverse) disease symptoms years were identified through the ClinicalTrials.gov database. meetings in 2009-2011 were included. SLE therapy clinical trials within the past five literature databases (EMBASE and MEDLINE/PUBMED). Conference abstracts from PSY37 PATIENT-REPORTED OUTCOME (PRO) ASSESSMENTS IN SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)

OBJECTIVES: Review the development and properties of PRO instruments used in clinical trials and observational studies of patients with SLE. METHODS: A structur ed search was conducted to identify published articles in 2005-2011 through key literature databases (EMBASE and MEDLINE/PUBMED). Conference abstracts from targeted rheumatology, outcomes research and quality-of-life (QoL) scientific meetings in 2009-2011 were included. SLE therapy clinical trials within the past five years were identified through the ClinicalTrials.gov database. RESULTS: Over 60 different PRO instruments were used in SLE-related research; 7 were lupus specific, 11 assessment general symptom and the rest assessed specific symptoms. (e.g., fatigue, pain) or other patient attributes (e.g., satisfaction, adherence). The SF-36, LupusQoL, and LupusPRO were most frequently used in SLE research. These instruments have 56, 54, and 43 items, respectively. All three instruments have a recall period of past four weeks; they demonstrated robust reliability and construct validity when used in SLE patient samples, but generally weak associations (r=0.12-0.29) with SLE disease-activity indices. Validated symptom-specific FACIT-Fatigue scale was also used in some studies to measure this important aspect of patient experience and it correlated with SLE disease-activity indices. Recently, 10 items from the LupusPRO were validated for use as ‘Lupus Impact Tracker’ (LIT) to retain the reliability and validity of the longer tool while decreasing questionnaire burden. Brief validated instruments used in rheumatic diseases (e.g, RAPID12: 15 items; RAPID7: 7 items). CONCLUSIONS: The SF-36, LupusQoL, and LupusPRO are the most widely used validated PRO instruments, but these have a varying degree of questionnaire burden and specificity to SLE symptoms. Shorter versions of validated PROs (e.g., SF-12, LIT) or instruments such as RAPID13 may minimize test-retest burden. The practicality of these PRO instruments for use in daily practice to discriminate clinically meaningful changes in patient-reported SLE treatment outcomes deserves further investigation.

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 (LBP) that patients report spontaneously and in response to probes during clinician 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 score of ≥14 on the 0-20 numerical rating scale (NRS) were included from 4 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 symptom/impact/concepts patients experienced by probe in order to assure full coverage of concept domains. Transcripts were coded using Atlas ti and summarized by distinct concepts. Inter view guide notations were used to tag each concept offered by spontaneous versus probed result. RESULTS: Forty-three patient interviews were conducted (mean age 55.0, 53.5% female, 44.6% White/Caucasian). Mean (SD) pain NRS for cLBP was 6.7(1.3). Spontaneously reported symptoms included: Numbness (51.2% of sub jects), 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 included: Feelings of stiffness (55% of 70 subjects), Fatigue (41.9%), Pressure (39.5%), Cramping (32.6), and Pins and Needles (30.2%). Spontaneously reported impacts included interference: with: Walking (65.1%), Sitting (62.8%), Exercise (58.1%), Leisure Activities (58.1%), Sleeping (55.8%), Household Chores (53.5%), and Emotional Impacts (48.8%). Impacts reported most often in response to probes included Low Energy because of pain (67.4%), Productivity (65.1%), Financial Impact (46.6%), Driving (39.5%), and Relationships (37.2%). CONCLUSIONS: Given the vari ety of symptoms and impacts described by patients as part of their cLBP experi ence, those reported spontaneously may be more relevant to patients compared to those reported upon probed. Conceptualization of symptoms and impacts 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: 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. Physically complete 36 questionnaire symmetry assessment (QoL), SF-36, BDI and SEILLC/ACR Damage Index, a physician’s global assessment (PGA) and patient’s recent flare status. Reliability was evaluated using internal consistency methods (Cronbach’s alpha) and test-retest methods (meta-class correlation). Convergent validity was evaluated by comparing LIT scores with scale scores from the SF-36v2, LupusQoL, and PHQ-9. Construct validity was evaluated by comparing mean LIT scores across patients that differed in PGA ratings and presence/absence of a recent flare. ANOVA and Student’s t-tests were used to test mean differences in LIT scores across patient groups. It was hypothesized that LIT scores would be lower among patients with a lower PGA rating and a recent flare. RESULTS: Internal consistency and test-retest reliabilities of LIT were 0.90 and 0.88, respectively. Convergent validity correlations ranged from -0.63 to -0.75 with SF-36v2 scales, from -0.42 to -0.75 with LupusQoL scales, and with the 0.75 with the PHQ-9. Mean LIT scores differed as hypothesized between patients with and without a recent SLE flare (t=2.11, p=0.038). The majority (>70%) of both patients and physicians found LIT to be acceptable and feasible to administer in a clinic setting. CONCLUSIONS: The LIT is a reliable and valid instrument for assessing the impact of SLE on patient’s functioning and well-being.

PSY40 HEALTH-RELATED QUALITY OF LIFE AND ANNUAL DIRECT MEDICAL COST OF PATIENTS WITH HAEMOPHILIA IN B FRANCE: THE EQOFIX STUDY

OBJECTIVES: Scarcity data is available on the economic burden associated with haemophilia B (HB). The aim of this study was to evaluate in a representative French HB population the impact on health-related quality of life (HRQOL) and to estimate the costs associated with management. METHODS: This is a pro spective cohort study in patients with moderate and severe HB with one year follow-up. Data collected included: patients’ demographic and clinical characteristics, severity status, therapeutic approach, FIX consumption and all other re sources used. Two types of HRQOL were used: generic (Kidney (57SF-36 for adults) and specific (QUAL-HIMO, specific to haemophilia patients). The French national health insurance perspective was considered to estimate the average annual cost using official cost database. RESULTS: A total of 155 patients were included by 27 centres, representing a coverage rate of 25% of the French global population suffering from severe and moderate HB: 104 adults (74 severe and 30 moderate) and 51 children (40 severe and 11 moderate). 30.4% of patients re

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