

symptom). The Health Assessment Questionnaire (HAQ) was used to measure functional status (scores 0–3). QoL was measured by the mental (MCS) and physical (PCS) component summary scores of the Short Form-8 (SF-8). Work/productivity loss was measured by the Work Productivity and Activity Impairment (WPAI) instrument. Comparisons were made between patients who currently use SC biologics versus those who discontinued treatment. **RESULTS:** Of the 2,200 survey respondents (72% female; average age = 49.6years), 386 (17.5%) used SC biologics. The average duration of RA was 12.4 years, with 14% reporting severe disease. The patient-reported mean scores were: morning stiffness 6.6, fatigue 6.8, pain 6.5, HAQ 1.6, MCS 43.9 and PCS 36.4. Patients reported 61.0% work impairment and 59.2% impairments in daily activity. Patients who had discontinued SC biologic therapy (N = 124, 32.1%) reported significantly worse scores in morning stiffness, fatigue, pain, and PCS (all $P < 0.05$) versus patients currently treated with SC biologics (N = 262, 67.9%). Patients who discontinued therapy had more work/activity loss; only activity impairment was statistically significant ($P < 0.05$). There was no significant difference in HAQ scores between groups. **CONCLUSIONS:** RA patients using current SC biologics still suffer from serious impairments in symptoms, functional status, QoL, and work/productivity. However, patients who discontinued SC biologic therapy have significantly worse symptom scores, physical functioning, and activity impairment compared with those currently being treated. Both findings indicate there is still an unmet medical need in RA patients.

PMS40

UTILITY AND QUALITY OF LIFE OF PATIENTS WITH OSTEOARTHRITIS TREATED WITH THE CYCLOOXYGENASE INHIBITING NITRIC OXIDE DONATOR (CINOD) NAPROXICINOD

Jonsson B¹, Pfister P², Holmstrom S³, Kobelt G⁴¹Uppsala University, Uppsala, Sweden, ²NicOx, Sophia Antipolis Cedex, France, ³NicOx, Sophia Antipolis, France, ⁴European Health Economics, Speracedes, France

OBJECTIVES: To estimate changes in quality of life (SF36®) and utility (SF6®) in patients treated with naproxinod, naproxen or placebo for 13 weeks, and to explore the effect of different disease measures on utility. **METHODS:** SF36® was available from 3 international ph 3 clinical trials in 2738 patients with knee or hip osteoarthritis comparing 2 doses of naproxinod (375 and 750 mg bid) to naproxen (500 mg bid) and placebo. Efficacy was based on the pain, function and composite scales of the WOMAC™ osteoarthritis index. Co-morbidity measures included hypertension (HT) which increases with NSAID therapy, body mass index (BMI) and diabetes. Changes in SF6® and individual SF36® domains were compared between the groups using ANOVA and Dunnett's 2-sided test. The effect of the WOMAC™ indices, BP, BMI and diabetes on utility scores was explored using multiple regression analysis. **RESULTS:** All SF36® subscales except mental health as well as utility changed significantly from baseline for all groups, and were correlated with changes in the WOMAC™ indices ($p < 0.001$). The change in the active groups was significantly better than placebo for pain and physical function (<0.05), but not significantly different between treatments. However, absolute changes in utility, pain, physical function and general health were generally larger for naproxinod 750 mg than naproxen 500 mg by around 10%. Utility scores correlated significantly with WOMAC™, and patients with high BMI and BP or diabetes had lower utility scores and worse WOMAC™ indices. Increase in utilities were larger for patients with 750 mg naproxinod than for the other groups. **CONCLUSIONS:** The slightly larger utility and quality of life changes with naproxinod 750 mg despite a similar effect as naproxen on WOMAC™ may be explained by a different side-effect profile and a neutral blood pressure effect.

PMS41

AN ASSESSMENT OF SELF REPORTED OUTCOMES IN A NATIONALLY REPRESENTATIVE SAMPLE OF ELDERLY PERSON DIAGNOSED WITH RHEUMATOID ARTHRITIS

Rajpura JB

St. John's University, Fresh Meadows, NY, USA

OBJECTIVES: To utilize WebTV technology as a tool to measure HRQOL in elderly persons having Rheumatoid Arthritis (RA) in a nationally representative sample and to describe their socio-demographic characteristics, medication use and other treatment choices. **METHODS:** A cross-sectional online survey research design. Random digit dialing (RDD) survey procedures were used to draw a sample of 550 elderly arthritic individuals from US households across 44 states. A subsample of 79 individuals previously diagnosed with RA completed SF-36v2 survey, as part of a larger study. Eight SF-36 domain scores and Physical and Mental Component Summary (PCS and MCS) scores were computed and compared with cross-sectional norms for general US population. **RESULTS:** Compared to the general population, our study sample performed poorly with respect to all the SF-36 domains except mental health (MH) and social functioning (SF) domains. RA is more prevalent in whites (96%) and males reported higher scores for all the eight SF-36 domains than females. About 92% of the sample reported the use of at least one available OTC arthritic medication; 58% of the sample was taking prescription drugs, while about 53% reported having used natural/herbal remedies for arthritis. A significant difference ($p = 0.003$) was found between males and females with respect to only PCS scores. Age was found to correlate negatively ($p < 0.005$) with PCS and MCS summary measures, particularly for individuals 70 years and older. **CONCLUSIONS:** WebTV is an effective survey administration tool for measuring HRQOL. As expected, elderly perform poorly on three of the SF-36 domains (PF, RP, BP) having the most physical factor content. Prescription drug use is fairly prevalent and use of OTC medications and other forms of treatment is popular in the population under study.

THE EFFECT OF LIFESTYLE CHOICES ON THE RISK OF IMPAIRMENT IN RHEUMATOID ARTHRITIS PATIENTS: AN ANALYSIS OF AEROBIC EXERCISE AND CIGARETTE SMOKING

Shah A¹, Plumb J¹, Brawer R¹, Tang B²¹Thomas Jefferson University, Philadelphia, PA, USA, ²Tecotoc Ortho Biotech, Inc, Horsham, PA, USA

OBJECTIVES: Through data analysis we will examine and identify the lifestyle factors that impact clinical outcomes of Rheumatoid Arthritis (RA) patients. **METHODS:** Patients' self-reported data was collected from the 2008 RA Patient Survey, an Internet survey of RA patients. We studied the effects of aerobic exercise (>20 minutes a day per month), and cigarette smoking on RA patients. Sign and symptom scores for morning stiffness, fatigue, and pain are defined from 0 (no symptom) to 10 (severe symptom) within the survey. The Health Assessment Questionnaire (HAQ) was used to measure functional status scores (0–3). Quality of life was measured by the mental component score (MCS) and physical component score (PCS) of the Short-Form 36 (SF-36). Productivity was measured by the Work Productivity and Activity Impairment (WPAI) Scale. There were no non-RA controls included in the study. **RESULTS:** A total of 2048 respondents were included in the analysis 1001 patients exercised and 584 patients smoked cigarettes. The average age was 51.9 years and average RA duration was 11.9 years. Patients' mean MCS and PCS scores in the exercise (40.7, 36.7) and non-smoking groups (41.2, 34.4) were significantly higher, than in the non-exercise (40.0, 31.3) and smoking groups (37.4, 32.7). Overall work and productivity impairment was 41.5% (exercise) versus 45.4% (non-exercise), and 45.5% (smoking) versus 42.2% (non-smoking). Signs, symptoms, and HAQ scores were significantly better in the exercise and non-smoking groups (all $P < 0.05$). **CONCLUSIONS:** RA patients who exercise regularly have higher quality of life scores and clinical outcomes. Those that smoke cigarettes have lower quality of life scores and higher symptom/HAQ scores suggesting that this habit may be detrimental to their clinical outcomes. These results suggest that these lifestyle choices influence the overall risk of impairment in RA patients.

PMS43

IS THE HEALTH UTILITIES INDEX VALID AND RESPONSIVE IN ASSESSING PATIENTS WITH ANKYLOSING SPONDYLITIS?

Gooch K¹, Feeny DH², Wong R³, Pangan A¹, Revicki D⁴, van der Heijde D⁵¹Abbott Laboratories, Abbott Park, IL, USA, ²Kaiser Permanente Center for Health Research, Portland, OR, USA, ³Abbott Laboratories, Parsippany, NJ, USA, ⁴United BioSource Corporation, Bethesda, MD, USA, ⁵Leiden University Medical Center, Leiden, Netherlands

OBJECTIVES: QALYs are an important outcome used in cost-effectiveness analysis. The Health Utilities Index Mark 3 (HUI-3) is a self-reported measure covering 8 attributes of health status. Our objective was to assess construct validity and responsiveness of HUI-3 in ankylosing spondylitis (AS). **METHODS:** Data were derived from the Adalimumab Trial Evaluating Long-Term Efficacy and Safety in AS (ATLAS). We specified *a priori* hypotheses regarding the direction and magnitude of associations expected between overall and single-attribute HUI-3 scores and other health status and quality of life measures—SF-36, ASQOL, Bath AS Functional Index (BASFI), Bath AS Disease Activity Index (BASDAI), and Patient's Global Assessment (PGA). Using baseline data, we calculated correlation coefficients and interpreted them via guidelines suggested by Guyatt for negligible, weak, moderate, and strong associations. Responsiveness was assessed by calculating standardized response means (SRMs) of HUI-3 scores from baseline to Week 24 for patients meeting the minimum clinically important differences (MCID) for the ASQOL (−1.8). Responsiveness analysis was limited to patients with 24-week HUI-3 scores. **RESULTS:** A total of 295 of the 315 patients enrolled in ATLAS were included in the analysis. Mean age was 43 years, 76.3% were male, and mean duration of AS was 11 years. Correlation coefficients between HUI-3 scores and other instruments confirmed 62.2% of the *a priori* hypothesis, with an additional 24.5% being under- or over-estimated by only one category. Results of responsiveness analysis demonstrated that there were significant differences in overall HUI-3 (SRM 1.13) and most single-attribute change scores for patients whose changes were greater than the ASQOL MCID vs. those whose changes were < MCID. **CONCLUSIONS:** These results suggest that HUI-3 constructs are related to similar constructs in other measures, as expected. This study provides evidence of cross-sectional and longitudinal construct validity of the HUI-3 for deriving utility scores for AS patients.

PMS44

VALIDATION OF THE MULTI-ATTRIBUTE HEALTH UTILITY (MAHU) DERIVED FROM A COMPUTER ADAPTIVE INSTRUMENT, CAT-5D-QOL, IN OSTEOARTHRITIS

Kang W¹, Sayre EC¹, Steininger G¹, Doerfling P³, Ratzlaff C¹, Esdaile J², Kopec J³¹University of British Columbia, Vancouver, BC, Canada, ²Arthritis Research Centre of Canada and Simon Fraser University, Vancouver, BC, Canada, ³Arthritis Research Centre of Canada, Vancouver, BC, Canada

OBJECTIVES: We aimed to validate the multi-attribute health utility (MAHU) derived from the CAT-5D-QOL, a computer-adaptive instrument composed of 5 domains (Walking, Handling Objects, Daily Activities, Pain/Discomfort, and Feelings) in people with self-reported osteoarthritis (OA), and to compare it with WOMAC_HUI3, the utility derived from the standard disease-specific measure in OA. **METHODS:** Data were collected from participants (age 50+) who completed questionnaires CAT-5D-QOL in two waves and WOMAC in one wave of a Canada-wide online survey. To assess construct validity, we used multivariable regression to examine the associations