IMPROVING THE SENSITIVITY OF PHYSICAL FUNCTION MEASURES IN RHEUMATOID ARTHRITIS: USE OF ITEM RESPONSE THEORY IN PATIENTS TREATED WITH ABATACEPT (CTLA4IG)

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OBJECTIVES: The Health Assessment Questionnaire (HAQ) and the Modified HAQ (MHAQ) are examples of common short-forms of physical function used to measure improvement in the treatment of rheumatoid arthritis (RA) which have been associated with ceiling problems. These problems, inherent to short-form surveys, pose risks of failing to detect a treatment response in clinical trials. Item Response Theory (IRT) methods were used to examine the properties of two physical function measures and construct a combined measure to better detect changes in disease activity and treatment response. METHODS: Data were from a 12-month, double-blind, multi-center study of 339 RA patients on a background of methotrexate randomized to Abatacept at 2 mg/kg, at 10 mg/kg, or placebo. MHAQ and SF-36 (with its Physical Functioning scale, PF10) were administered at pretreatment and 3, 6, and 12 months post-treatment. IRT methods were used to examine the surveys’ measurement properties and compute new IRT-based physical function scores. Analyses of variance were used to assess sensitivity to changes in disease severity and treatment response. Relative validity coefficients were used to compare the measures. RESULTS: A Rasch IRT model fit the data. IRT-based scores successfully lowered the floor and raised the ceiling of the physical function measured. IRT-based scores were 30% more efficient than MHAQ and 50% more efficient than PF10 in discriminating among ACR groups. In discriminating among treatment groups, IRT-based scores were 25% more efficient than MHAQ and 12% more efficient than PF10 at 6-months; and 16% and 17% more efficient at 12-months based on observed effect sizes. CONCLUSIONS: Using IRT methodology to estimate a combined score for physical functioning lead to greater range of the construct measured. The improved measure, with greater measurement precision and sensitivity to treatment response, further confirmed the beneficial effect of Abatacept on physical function in the treatment of RA.

REVALIDATION OF THE CEDARS-SINAI RHEUMATOID ARTHRITIS HEALTH-RELATED QUALITY OF LIFE (CSHQ-RA) SHORT FORM INSTRUMENT

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OBJECTIVE: This study reassessed the psychometric performance of the 11-item CSHQ-RA Short Form using a representative population of RA patients from 55 sites across the US. METHODS: 307 of 309 screened patients from a 24-week multicenter, open-label, single arm study of RA patients receiving anakinra completed the CSHQ-RA, the Medical Outcomes Study Short Form-36 (MOS SF-36) and the Stanford Health Assessment Questionnaire (HAQ) Disability Index. Data at screening and baseline were used to examine the convergent validity, discriminant validity, internal consistency, and test-retest reliability. Convergent validity was tested, using Pearson’s correlations, by comparing total score on the CSHQ-RA to those from the Mental and Physical Component Summary (MCS and PCS) of the MOS SF-36 and HAQ. ANOVA and Kruskal-Wallis tests were used to assess the discriminant validity of the CSHQ-RA. Internal consistency was measured by Cronbach’s alpha coefficient. Test-retest reliability was assessed using intraclass correlation coefficient (ICC). RESULTS: Response rate at baseline was 95% (291). 81% of respondents were female; mean age was 52 years (±12); mean duration with RA was 10.8 years (±10.4). Mean scores were CSHQ-RA Short Form 68.0 (±16.0), MCS 37.9 (±10.9), PCS 31.2 (±8.3), and HAQ 1.5 (±0.7). Pearson’s correlations with MCS, PCS, and HAQ were −0.69, −0.70, and 0.76 (P < 0.0001), respectively, demonstrating good convergent validity. The difference in scores on the CSHQ-RA Short Form of patients with different levels of physical disability as measured by the HAQ was statistically significant (P < 0.0001). Cronbach’s alpha coefficient was 0.89, indicating good internal consistency. Test-retest reliability was great with ICC equal to 0.94. CONCLUSIONS: The results of this study support the validity and reliability of the 11-item CSHQ-RA Short Form as a measure that captures the impact of RA on patients’ quality of life. Research to assess responsiveness and clinically significant change of the CSHQ-RA is under way.
was included in the overall estimate of WTP. CONCLUSIONS: The results from this study illustrate the value that OA patients attribute to the reduction in GI-side effects associated with Cox-2 selective inhibitors such as VIOXX. On average, patients were willing to pay $157.85 per month for a medication that specifically reduced the risk of both complicated and uncomplicated PUBs.

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BURDEN OF OSTEOARTHRITIS AND ITS TREATMENT ON PATIENTS
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OBJECTIVES: We describe pain level, medication use, potential medication-related events, perceived medication effectiveness, and medication switching among osteoarthritis (OA) patients.

METHODS: Patients totaling 4386 with self-reported OA completed an internet survey. Recent OA pain level was reported on a 0–10 scale (10 = “worst possible” pain). Respondents reported regular Rx and OTC medication use, and potential side effects is high. Only 1 in 4 patients in our sample perceived their OA medications to be effective, and most reported experiencing at least some OA pain despite regular medication use.

RESULTS: Demographics: Mean age 55.3 years, 70.8% female, 91.4% white. Average recent OA pain was 4.9. 70.1% reported pain in 3 joints. 28.0%, 27.8%, and 32.2% reported taking only OTC, only Rx, or both on a regular basis, respectively. Twenty-five percent felt their OA medications were slightly or not effective; 54.1% felt they were only moderately effective. A total of 34.4% switched or discontinued medication(s) during the past year; 41.5% and 35.1% of these patients cited lack of effectiveness and/or side-effects as a reason, respectively. Respondents using both Rx and OTC OA medications experienced potentially medication-related events more frequently than those not taking medication. Patients who switched OA medications reported experiencing higher recent OA pain, GI events (compared to non-GI), pain in more than 6 joints, and more than 3 events potentially related to medication use and were more likely to be female (all p < 0.05). CONCLUSIONS: The burden of OA on patients in terms of pain, medication use, and potential side effects is high. Only 1 in 4 patients in our sample perceived their OA medications to be effective, and most reported experiencing at least some OA pain despite regular medication use.

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CONTRIBUTION OF PAIN, SITE OF PAIN AND NUMBER OF JOINTS AFFECTED ON PRODUCTIVITY LOSS AMONG WORKERS AND NON-WORKERS WITH OSTEOARTHRITIS
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OBJECTIVES: We examined productivity hours lost due to pain, site of pain, and number of joints affected among workers and non-workers with osteoarthritis (OA).

METHODS: A total of 4386 self-reported OA patients completed an internet survey. Respondents reported previous week’s work or daily activity hours lost due to OA, OA pain (scale 0–10, 10 = “worst possible” pain over 24 hours), site(s) of pain, and affected joint(s). Impact of pain, number of affected joints, and site of pain on total hours lost was evaluated using generalized linear regression and including a pain-level-employment interaction.

RESULTS: Demographics: mean age 55.3 years, 70.8% female, 91.4% white. Average recent OA pain was 4.9. Average hours lost were 10.2 (SD 24.1). Non-workers reported more hours lost (18.2 vs. 1.7; p < 0.0001) and higher pain (5.4 vs. 4.5, p < 0.0001) than workers. Higher pain was associated with increased lost hours for both groups, but more so for non-workers (p < 0.0001). Both workers and non-workers with pain in >7 joints lost significantly more hours than those with fewer affected joints (3.5 vs. 1.4 for workers, 31.6 vs. 14.1 for non-workers, p < 0.0001). Lost hours were significantly greater for lower vs. upper body pain for both groups (1.5 vs. 0.5 for workers, 10.9 vs. 3.6 for non-workers, p < 0.0001). Higher pain, pain in >7 joints, low back pain, and pain-employment interaction predicted hours lost due to OA (all p ≤ 0.05) after controlling for age, race, gender, education, employment, income, and regular medication use. Specific joint sites did not predict lost hours. The pain and pain-employment interaction parameters indicate that non-workers lose more hours than workers at every pain level and this differential increases with higher pain. CONCLUSIONS: Recent OA pain and the number of affected joints but not individual pain site(s) impacted productivity. These effects were greater for non-workers who likely have more severe OA symptoms.