CONCLUSIONS: The PsAQoL is a measure of quality of life (QoL) specific to psoriatic arthritis (PsA). A phase IIb study was conducted in 2003. Concluding this measure was derived from qualitative interviews conducted with UK PsA patients. New language versions have since been developed for several European countries, the US, Canada, Argentina and Brazil. Interest in the PsAQoL has increased lately due to the need to determine changes in QoL associated with new biological treatments. In recent years there has been a move towards conducting clinical trials in developing countries. This has increased interest in adapting patient-reported outcome measures developed in Europe and the United States for use in new regions of the World. An important question remains to be answered: can such measures provide valid assessment of QoL in these regions? METHODS: New adaptations are currently being produced for Eastern Europe (the 4), the Middle East (2), Central and South America (2) and Asia (5). The measures are being translated (using the two panel methodology required for needs-based measures) and tested with local patients by means of cognitive debriefing interviews. RESULTS: To date cognitive debriefing interviews have confirmed the adapted measures’ acceptability to patients who had found it easy to understand and complete. The adaptations also have good internal consistency (alphas > 0.85) and reproducibility (test-retest reliability coefficients: > 0.85). The adaptations also exhibited construct validity by their ability to distinguish groups of PsA patients that varied by perceived disease severity and general health and by correlating as expected (moderately) with the Nottingham Health Profile. CONCLUSIONS: It is intended to use Item Response Theory analyses to determine whether respondents in the developing countries answer the PsAQoL in the same way as their Western country counterparts. This will show whether the scales work validly in the developing countries.

Sensitivity of PRO’s to Detect Changes in Quality of Life in Patients Treated with a Biologic Agent

Pamford I1, Wade A2, Crawford G3, Mcconnachie A4

OBJECTIVES: To investigate whether patient reported outcomes in patients who had been prescribed etanercept, an anti-TNF inhibitor, by their specialist could detect changes in quality of life over time. A longitudinal evaluation was designed to compare outcomes with those from their long-term use of previous medications and 12 months of biological treatment. METHODS: The evaluation was conducted throughout the UK using a web-based system supplemented by telephone reporting (PROBE; patient reported outcomes based evaluation). Outcome measures included demographic data, the assessment of chronic illness therapy—fatigue (FACIT-F), health assessment questionnaire—disability index (HAQ-DI), pain visual analogue scale (VAS), and SF-36 domain scores. Correlations between the HAQ-DI, pain VAS, and FACIT-F and the SF-36 physical function (PF), bodily pain (BP) and vitality (VT) domains were described with statistical significance. RESULTS: At week 12, mean change in SF-36 BP, and VT was −2.1, 2.7, and 3.1 with placebo; 6.2 (P = 0.012 versus placebo), 11.5 (P = 0.001 versus placebo), and 6.6 (P = 0.005 versus placebo) with APR20; and 3.8, 7.9 (P = 0.002 versus placebo), and 7.7 with APR40, respectively. Mean change in HAQ-DI was −0.1, −0.2, and −0.2 with placebo, APR2O, and APR40. Mean change in FACIT-F was 0.5, −0.1 (P = 0.025), and −4.3 with placebo, APR20, and APR40. Mean percent change in pain VAS was 7.4%, −14.5%, and −15.1% with placebo, APR20, and APR40. Moderate (≥0.30) and statistically significant (P < 0.001) correlations were consistently found on pain VAS (r = 0.550, P < 0.001) but not for FACIT-F and VT (0.55). High (r = 0.60), statistically significant (P < 0.001) correlations were observed for FACIT-F versus VT (0.66) with APR20 and HAQ-DI versus PF (r = −0.73) with APR40. CONCLUSIONS: Treatment of PsA with APR20 was associated with statistically significant improvements versus placebo in FACIT-F and HRQoL. Moderate to high correlations were evident among PROs.