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Presentation Number: 1192

BACKGROUND: Health-related quality of life (HRQL) has become an important outcome measure in daily clinical practice and research. Several disease-specific and generic measures have been developed to assess HRQL. Where disease-specific measures are more likely to reveal responses, generic measures, like the Short-Form-36 (SF-36), allow comparison between diseases. Optimal sensitivity to change is mandatory to improve healthcare research.

PURPOSE: The aim of this study was to examine the sensitivity to change of the SF-36 in comparison with disease-specific HRQL measures in Dutch patients with rheumatoid arthritis (RA).

METHODS: A total of 277 consecutive RA patients starting any TNF-blocking treatment were enrolled from ten rheumatology centres in the Netherlands. Patients completed a questionnaire including the SF-36, Arthritis Impact Measurement Scales 2 (AIMS2), Health Assessment Questionnaire (HAQ), Visual Analogue Scale (VAS) for global health, and 11-point box scale for pain intensity at baseline and after 3 months. Changes in scores over 3 months were evaluated with paired t tests and standardized response means (SRM), calculated as the mean change score divided by the standard deviation of the mean change score. Values of 0.20-0.49, 0.50-0.79, and ≥ 0.80 were considered to represent small, moderate and large degrees of sensitivity to change, respectively.

RESULTS: All SF-36 subscales showed significant changes in health status after 3 months of TNF-blocking treatment (p ≤ 0.02). Small clinical changes were found for the subscales mental health (SRM -0.33), social functioning (SRM -0.46), role-emotional (SRM -0.21), vitality (SRM -0.49) and general health (SRM -0.22). Moderate clinical changes were found for the subscales physical functioning (SRM -0.60) and role-physical (SRM -0.57). Large clinical change was found for the subscale bodily pain (SRM -0.85).

No differences in sensitivity to change were found between the SF-36 and the disease-specific measures (AIMS2, HAQ) concerning the domains physical functioning, mental functioning and pain. Only the box scale for pain intensity was less sensitive (SRM 0.73). Within the domain of social functioning the SF-36 (SRM -0.46) was more sensitive than the AIMS2 (SRM 0.10). Within the domain general health the AIMS2 (SRM 0.54) and VAS global (SRM 0.60) were more sensitive than the SF-36 (SRM -0.22).

CONCLUSIONS: The sensitivity to change of the SF-36 subscales in Dutch RA patients after 3 months of TNF-blocking treatment varied from small to large with higher degrees of sensitivity for the physical scales. Compared with disease-specific measures (AIMS2, HAQ) the SF-36 subscales showed similar degrees of sensitivity except for the general health subscale, which was less sensitive, and the social functioning subscale, which was more sensitive.

M.M. Veehof, None.