GO11UMAB SIGNIFICANTLY IMPROVES PRODUCTIVITY IN PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS: RESULTS FROM THE PHASE 3 GO-RAISE STUDY

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OBJECTIVES: To evaluate the impact of golimumab (GLM) on productivity in ankylosing spondylitis (AS) patients.

METHODS: GLM was studied in a multicenter, randomized, placebo (PBO)-controlled study (GO-RAISE). A total of 356 patients were randomized (1.8:1.8:1 ratio) to receive subcutaneous GLM 50 mg or 100 mg or PBO q4wks. Patients with AS according to the modified NY criteria (BASDAI and back pain score each ≥4) were eligible. Productivity was measured on a VAS scale (0–10 cm). Change in productivity from baseline to wk16 and wk24 was compared between groups. At wk16, patients in the PBO or GLM 50 mg group who had ≥20% improvement in total back pain and morning stiffness measures entered early escape in a double-blind fashion. All other patients remained on their previous medication until wk24. For GLM 50 mg or PBO patients who entered early escape, their last observation prior to their previous medication until wk24. For GLM 50 mg or PBO 100 mg groups at wk16 and wk24.

RESULTS: Patients in the GLM 50 mg group vs. PBO at wk16 (−2.8 ± 3.0 vs. −0.4 ± 2.7; p < 0.001) and wk24 (−2.7 ± 3.1 vs. −0.5 ± 3.0; p < 0.001), and also significantly greater in the GLM 100 mg group vs. PBO at wk16 (−2.9 ± 2.9 vs. −0.4 ± 2.7; p < 0.001) and wk24 (−2.9 ± 3.0 vs. −0.5 ± 3.0; p < 0.001). The change from baseline in productivity was similar in the GLM 50 mg and GLM 100 mg groups at wk16 and wk24. CONCLUSIONS: A patients treated with GLM 50 mg and 100 mg had significant improvement in self-reported productivity, with improvement at wk16 maintained through wk24.

PODIUM SESSION III: QUALITY OF LIFE/ PREFERENCE-BASED MEASURES III:
NOVEL INSTRUMENTS

DEVELOPMENT AND VALIDATION OF AN ELECTRONIC VERSION OF THE HEALTH ASSESSMENT QUESTIONNAIRE DISABILITY INDEX (HAQ-DI)

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OBJECTIVES: To develop an electronic version of the Health Assessment Questionnaire Disability Index (HAQ-DI) for use on a handheld computer and to assess the equivalence of the electronic and paper versions in patients with rheumatoid arthritis.

METHODS: Development of the electronic version involved significant modification, in particular eliminating free text entry. The conceptual framework of the scale was not altered, and the electronic version was aligned to the original scoring scheme. Equivalence of scores was evaluated in a crossover study in which patients completed a series of questionnaires including the HAQ-DI once in electronic and once in paper mode in randomised order with a 45-minute interval in between. Patients then completed a questionnaire on ease of use and acceptability of the two modes. Agreement was assessed using intraclass correlation coefficients (ICC), mean differences between electronic and paper scores, and Bland-Altman plots. RESULTS: Forty-three patients, 12 male and 31 female, aged 32–83 years, completed the study. Overall agreements between the paper and electronic questionnaires was excellent (HAQ-DI: ICC = 0.963). Comparison of mean differences showed no evidence for bias in electronic vs. paper scores. The mean difference between electronic and paper scores was 0.03 units (S.D. 0.20), corresponding to 1% of the total scale length. Most patients found both paper and electronic questionnaires easy to use, and all patients found both modes acceptable. Six patients preferred paper, 23 preferred electronic, and 14 expressed no preference. CONCLUSIONS: There was excellent agreement between electronic and paper administration of the HAQ, suggesting that migration from paper to electronic had not led to any significant change in the data collected. Electronic methods of data collection were well-liked by patients and highly acceptable. The results support the use of the electronic version of this scale in clinical studies in rheumatoid arthritis.

DEVELOPMENT AND VALIDATION OF THE SATISFACTION WITH MEDICATION QUESTIONNAIRE (SAT-Q) IN PATIENTS WITH CHRONIC DISEASE

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OBJECTIVES: To develop and validate a brief general questionnaires to assess patients’ satisfaction with pharmacological treatment in chronic diseases. METHODS: An extensive literature review was conducted to create an initial item pool of 41 questions regarding, exclusively, satisfaction with medication. Next, two physicians and two English-Spanish translators carried out item forward-backward translation into Spanish. Moreover, comprehension and importance of items (IUI) were assessed by experts’ (5 physicians, 2 nurses and 1 psychologist) and patients’ (n = 30) panels leading to an initial version of 20 items. Finally, scale item reduction and validation (feasibility, reliability and validity properties) of the final SAT-Q were carried with patients from 4 Primary Health Centres. RESULTS: In total 202 patients (65.35% female) were collected and 196 patients (97.5%) completed the questionnaire correctly. Exploratory factorial analysis (FA) and item-total correlation lead to a reduced final questionnaire (13 items). Confirmatory FA (oblimin rotation) revealed 1 general domain, global satisfaction (3 items, 72.35% of variance explained, Cronbach’s α: 0.81) along with 4 specific domains (eigenvalues >1.0): side-effects (3 items, 32.49% of variance explained, Cronbach’s α: 0.76) oversights (2 items, 14.85%, Cronbach’s α: 0.71), treatment effectiveness (3 items, 13.92%, Cronbach’s α: 0.74), adherence (2 items, 10.23%, Cronbach’s α: 0.53). Overall, test-retest correlations (n = 30) were significant (p < 0.001): global satisfaction (0.69), treatment effectiveness (0.63); side-effects (0.46), adherence (0.64) oversights (0.88). Correlations between domains and Physical and Mental Summary Components of SF-12 Health Survey were respectively: global satisfaction (0.39 and 0.50; p < 0.001), treatment effectiveness (0.33 and 0.19 p < 0.001); side-effects (0.35 and 0.35;