98.6% of patients had 2 or more fractures after age 40 years, the mean (SD) number of fractures was 4.2 (1.7) and median number was 4.0 (interquartile range 3.0–5.0). During the study, the mean (SD) duration of treatment by teriparatide was 443 (203) days, at the end of 17th month, 67.9% of patients were still on treatment. The main reasons of treatment discontinuation were treatment completion (69.9%), adverse events (14.5%), patient decision (14.0%), and physician decision (2.2%). Between baseline and end of study, the rate of women with back pain decreased from 93.8% to 83.3% and 37.1% had an improvement in the severity, mean (SD) back pain intensity (VAS) decreased from 55.9 (24.8) to 35.0 (24.2), and mean (SD) EQ-5D VAS increased from 52.6 (19.4) at baseline to 57.8 (21.4) at end of study. CONCLUSIONS: French patients with severe osteoporosis treated with teriparatide in a routine setting had an increase in quality of life and a decrease in back pain during the teriparatide treatment period and post-treatment follow-up. The results should be interpreted in the context of a non-controlled observational study.

PMSS9

THE EFFECT OF TNF THERAPY, SOCIODEMOGRAPHIC AND CLINICAL FACTORS ON SLEEP DISTURBANCES AND FATIGUE AMONG RHEUMATOID ARTHRITIS—RESULTS FROM THE NDB-PORUGAL COHORT

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BACKGROUND: The prevalence of sleep disturbances and fatigue among patients with rheumatoid arthritis (RA) is high. TNF therapy reduces disease activity and disability in RA, but few studies have analyzed the impact of TNF vs. traditional DMARD therapy, sociodemographic and clinical factors on sleep and fatigue, in prospective cohorts. OBJECTIVES: We assessed the effect of TNF therapy, sociodemographic and clinical factors on sleep disturbances and fatigue in RA patients. METHODS: A total of 1,082 RA patients from the NDB-Portugal cohort participated in this prospective study. Patients’ last observation was used. Univariate (UV) and multivariate (MV) linear regression models (β, 95% CI) assessed the impact of the following on sleep disturbances (measured by the sleep disturbance scale (VAS 0–10, 10 is worst)) and the insomnia severity index (0–28, 28 is worst)) and fatigue (VAS 0–10, 10 is worst)); traditional DMARD and TNF therapy, age, sex, education level, marital status, number of major comorbidities, RA duration, disability (HAQ-DI 0–3, 3 is worst), quality of life (VASQOL 0–1, 1 is best), emotional distress (Hospital Anxiety and Depression Scale—HADS 0–21, 21 is worst) and prednisone use. RESULTS: In MV, TNF therapy seemed to decrease fatigue (β = −0.60 (−1.08, −0.11)) when compared to traditional DMARDS and although nor statistically significant, increased sleep disturbances (β = 0.46 (−1.04, 0.13)) and insomnia β = −0.32 (−1.16, 0.73)). An increase in sleep disturbances was seen with worse HAQ (β = 0.64 (2.53, 1.02)), lower VASQOL (β = −1.46 (−2.63, −0.28)), more anxiety symptoms: (β = 0.19 (0.09, 0.29)) and higher fatigue (β = 0.26 (0.17, 0.36)). These results were also seen for insomnia and fatigue. More sleep disturbances (0.18 (0.12, 0.25)) increased fatigue and higher fatigue increased insomnia (0.39 (0.23, 0.54)). CONCLUSIONS: We found that the use of TNF therapy improved fatigue when compared to traditional DMARDs. Higher disability and worse quality of life increased sleep disturbances, insomnia and fatigue.

TNP THERAPY REDUCES THE ODDS OF WORSENING DISABILITY TRENDS IN RHEUMATOID ARTHRITIS OVER AT LEAST 2 YEARS—DATA FROM THE NDB-PORUGAL COHORT

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OBJECTIVES: Many studies have identified predictors of the health assessment questionnaire (HAQ), but few have evaluated the predictors of HAQ trends among RA patients. To investigate the predictors of worsening disability trends compared to other patterns among RA patients over at least 2 years. METHODS: A total of 666 RA patients from the ongoing biannual NDB-Porugal cohort with at least four consecutive HAQ scores per patient during their follow-up were used. The proportion defined by the number of 6-month positive increments in HAQ scores (worsening function) divided by the total number of differences was computed per patient and used to define a patient trend. The outcome was then defined as the presence of a trend of worsening disability (when proportion >0.5). This meant that a patient’s tendency of worsening was higher than their tendency of improving during their own follow-up. Univariate (UV) and multivariate (MV) generalized estimating equations (GEE) were used to study the predictors of worsening disability trend. Age, education, disease duration, paid work, retirement, number of total major comorbidities, SF-36 mental component, RADAI, the VAS scales of sleep, fatigue and pain, the use of current TNF (with or without concomitant DMARDs) vs. traditional DMARD therapy and steroids, were used as possible predictors. RESULTS: A total of 356 (26%) patients had worsening disability trends. The UV analyses showed that all of the following factors were statistically relevant: age, educational level, number of major comorbidities, sleep disturbances and fatigue, RADAI and the use of TNF therapy. The final MV model included pain (OR: 1.103 (95% CI: 1.000; 1.005)), age (OR: 1.012 (1.001; 1.012)) and the use of TNF (OR: 0.94 (0.91; 0.97)). CONCLUSIONS: In our study, we showed that older age and more pain predicted worsening HAQ disability trends. The use of TNF therapy was the only factor that decreased the odds of having a worsening HAQ trajectory.

PM561

RELATING OSTEARTHRITIS AFFECTATION, FUNCTIONAL DISABILITY AND QUALITY OF LIFE: A STRUCTURAL EQUATION MODEL. THE EXPECT STUDY

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OBJECTIVES: To establish a conceptual model which relates osteoarthritis (OA) afectionation, functional disability in daily activities, and Quality of Life (QoL). METHODS: The present is an observational, cross-sectional, multicenter study. OA presence/absence, by location, was clinically recorded. Disability was assessed with the Health Assessment Questionnaire Disability Index (HAQ-DI), Qol through the EuroQol-5D questionnaire. Descriptive were used sociodemographic and clinical variables; relationship between OA, disability and QoL was estimated through Structural Equation Modeling (SEM). This multivariate analysis technique allows to hypothesize multiple relationships among latent, unobserved variables and tests the model with a equation system. RESULTS: A total of 965 OA patients were included [mean age = 64 years (SD = 11); 75% women]. Mean body locations affected by OA was 2.81 (median = 2; SD = 1.613). The most frequently affected locations were knees (67% of the patients), lumbar (60%) and cervical (45%) spine. Regarding EuroQol-5D, most patients reported not having severe problems in the five areas assessed. Other predictors, such as disability and the use of steroids on a marginal adjustment (CMIN/DF = 5.42, RMSEA = 0.026; RMSEA = 0.069). CONCLUSIONS: With the available data, the functional disability can account for the decrease in QoL. Theoretically, OA is strongly related with disability and QoL, but the model fail to fully explain this link. As statistical techniques need good measurement models to accurately estimate relationships, standard clinical records seem insufficient for this purpose. Additional valid measurements of OA afectionation would be needed, to give evidence of its direct effect on disability and QoL.

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CERTOLIZUMAB PEGOL MONOTHERAPY PROVIDES SUSTAINED IMPROVEMENTS IN HOUSEHOLD PRODUCTIVITY AND DAILY ACTIVITIES IN PATIENTS WITH ACTIVE RHEUMATOID ARTHRITIS OVER 2 YEARS

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OBJECTIVES: To evaluate the impact of certolizumab pegol (CZP) monotherapy on household work and daily activities in RA patients over 2 years. METHODS: Patients in the FAST4WARD Phase II trial were randomised to CZP 400 mg every 4 weeks (Q4W) or placebo for 24 weeks. Those who completed or withdrew at/after Week 12 were eligible to enter an open-label extension (OLE) study of CZP 400 mg Q4W. This analysis focuses on CZP completers who entered the OLE study and had 2 years (100 weeks) of CZP exposure from baseline. Household productivity and impact on family/social/leisure activities were assessed using the validated Work Productivity Survey (WPS-RA). Analyses were conducted on observed data. RESULTS: Sixty-nine CZP completers entered the OLE. At BL, mean disease duration: 9.5 years; mean HAQ-DI: 4.12; mean DAS28-3(CRP): 5.76. Duration of RA on household productivity at BL was substantial: mean 10.1 household work days missed/days worked, 12.1 household work days with reduced productivity/month, 5 days missed/month of family/social/leisure activities. At Week 100, compared with BL, patients receiving CZP monotherapy reported on average fewer household work days missed per month (1.0 vs. 10.1), fewer days with reduced productivity in the home (1.1 vs. 12.1), reduced interference of RA on household productivity (2.0 vs. 5.8 on a 0–10 scale), fewer missed days of family/social/leisure activities (0.3 vs. 5.0). Improvements were seen as early as Week 4 and were sustained until Week 100. Over 12, 52 and 100 weeks, mean annualised cumulative gains from BL were 20.5, 108.4 and 199.3 household work days, respectively, 25.1, 136.0 and 244.9 more productive days within the home and in RA patients’ abilities to engage in family/social/leisure activities. CONCLUSIONS: CZP 400 mg Q4W monotherapy provides sustained improvement in productivity within the home and in RA patients’ abilities to engage in family/social/leisure activities.