PMS54

GAP BETWEEN PATIENT-REPORTED ESTIMATION ON FRACTURE RISK AND THE WHO ASSESSMENT TOOL (FRAX®) IN POSTMENOPAUSAL OSTEOPOROSIS

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OBJECTIVES: The FRAX® model recently developed by the WHO calculates 10-year probability of major osteoporotic and hip fracture, offering new basis for medical decision making and health economic analysis in osteoporosis (OP). [http://www.shef.ac.uk/FRAX/]. Patients' ideas regarding fracture risk and longevity might influence their perception of 10-year fracture risk data and compliance, and as a consequence, successful implementation of FRAX® based thresholds in everyday OP care. Our aim was to study whether FRAX® data differ from OP patients' and attendant especialists' self-estimations on fracture risk. We also assessed expectations on longliving which is a crucial point to perceive the 10-year farcture risk projection of FRAX® relevant. **METHODS:** In 2009 a cross-sectional survey was performed in 10 Hungarian rheumatology centres. Postmenopausal OP patients appearing on routine visit and switching to second line antiporotic drug were involved. Demographics, main clinical characteristics were registered. Patients' estimation on 10-year fracture risk and longliving were surveyed. Physicians' expectations on patients' perspectives were likely detected. FRAX® was calculated and matched with the estimations. **RESULTS:** 224 patients were involved, mean(SD): age 69.5(8.9)years, duration of OP care 6.7(5.1) years, lumbar Tsc-3.17(0.82), femoral Tsc-2.69(0.87), 133(59.4%) patients had OP fracture previously. Health status VAS was 59(17)mm. FRAX®-major OP fracture was 26(15.7)%, patients estimated 32.7(25.8)%, physicians marked 29.9(21.4)%. Results for hip fracture were: FRAX® 12.6(15.3)%, patients 26.7(25.3)%, physicians 21.5(19.1)% ($P < 0.01$). Patients' expected to live until age 82.4(8.2)years, physicians' estimation was nearly same (82.5, SD7 yrs). Less than 10-year survival was expected by 42,4% and 33.7%, respectively. **CONCLUSIONS:** Both patients and physicians overestimate fracture risk, especially for hip. Patients often expect to live shorter than the time-frame of the fracture risk projection. These aspects should be highly considered in health communication and also in the application of the FRAX® method in clinical practice.

PMS55

ANALYSIS ON THE POSSIBLE ASSOCIATION BETWEEN RHEUMATOID ARTHIRITIS AND DIABETES MELLITUS TYPE 2

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OBJECTIVES: Rheumatoid Arthritis (RA), a chronic inflammatory disease, may predispose to the development of Type 2 Diabetes Mellitus (T2DM). We aimed to compare incidence rates of T2DM in RA versus non-RA populations and study the influencing factors. **METHODS:** The study population consisted of participants in the National Data Bank for Rheumatic Diseases (NDB), where patients with rheumatologic disorders completed semiannual questionnaires, from 1998 through 2008. Osteoarthritis (OA) patients were used as controls. T2DM was determined based on self-reports of disease and on the use of hypoglycemic medication. The association between RA and T2DM was investigated using COX logistic regressions adjusted for relevant clinical and demographic covariates. **RESULTS:** A total of 14,481 participants diagnosed with RA (79.5% female; mean age 58.1 years) and 3,441 participants diagnosed with OA (84.5% female; mean age 63.6 years) were followed during 69,943 person-years. RA subjects had lower Body Mass Index (BMI) and less major comorbidities than controls. In patients with RA the T2DM incidence rate was 10 per 1000 person-years, while the incidence rate for OA was 15 per 1000 person-years. Both rates are superior to most estimates calculated among the US population. However, the covariate-adjusted risk of T2DM in patients with RA versus OA was not significant (HR = 0.94; 95% CI: 0.79–1.12, p = NS). Male gender, age, BMI, non-caucasian ethnicity, major comorbidities, low education level and prednisone intake were significantly associated with the incidence of T2DM. Some RA drugs had a clear protective role on TDM2, mainly methotrexate (19% risk reduction; p = 0.022) and hydroxicloroquine (47% risk reduction; $P < 0.001$). **CONCLUSIONS:** RA *per se* is not associated with increased risk of T2DM. Both RA and OA are associated with known TDM2 risk factors, such as BMI and some comorbidities, increasing the incidence rates of TDM2. Some drugs for RA treatment have a significant protective effect on the TDM2 risk.

PMS56

DETERMINING THE OPTIMAL TIMING FOR TOTAL KNEE REPLACEMENT

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OBJECTIVES: Total knee replacement (TKR) is a commonly used surgical procedure for patients with severe joint damage caused by arthritis; however, there remain difficulties in establishing criteria to define the optimal timing for TKR. The aim of this study was to identify the preoperative threshold HRQoL scores that were associated with better postoperative outcomes and those associated with greater improvement. **METHODS:** Data were collected from 1715 patients undergoing TKR between 2001 and 2006. Patients were interviewed at baseline and at 6 months and 2 years after surgery. At all three interview sessions, patients were asked to complete the Short-Form (SF-36) and the Oxford Knee Score (OKS). As physical function and pain have been identified as the key domains in osteoarthritis, the OKS and the physical functioning (PF) and bodily pain (BP) scales of the SF-36 were selected as the outcome measures of this study. Summary statistics were computed for preoperative, postoperative, and improvement in outcome scores. Visual inspection of the simple error bar charts were used to identify the threshold preoperative scores that were associated with better postoperative scores and those associated with more improvement. **RESULTS:** Patients with poorer preoperative HRQoL had worse postoperative outcomes but experienced greater improvement after TKR compared to those with better preoperative HRQoL. The highest postoperative PF scores are associated with a preoperative PF score of 50 points and above, whereas the baseline threshold OKS score was between 35 and 40 points. a baseline PF score of <30 points and an OKS score of >40 points are associated with the greatest improvement. No clear leveling off pattern was observed in the BP scores. **CONCLUSIONS:** PF and OKS threshold scores associated with optimal outcomes of TKR were identified in this study. Future research is needed to examine the predictive value of the scores identified in improving patients' post-operative outcomes.

PMS57

HEALTH-RELATED QUALITY OF LIFE AFTER TOTAL KNEE REPLACEMENT OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IN AN URBAN ASIAN POPULATION

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OBJECTIVES: To examine health-related quality of life (HRQoL) following total knee replacement (TKR) or unicompartmental knee arthroplasty (UKA). **METHODS:** Asian adult patients undergoing either TKR or UKA in a hospital of Singapore between 2001 and 2006 were interviewed before surgery and 6 and 24 months postoperatively to obtain demographic information and HRQoL scores using the Short-Form (SF-36) and the Oxford Knee Score (OKS). **RESULTS:** Data were collected from 2243, 1715, and 1113 patients at baseline, 6, and 24 months, respectively. TKR patients had a lower preoperative score than UKA patients on OKS and four subscales of the SF-36 ($p < 0.01$). Both TKR and UKA patients' OKS and SF-36 subscale scores improved six months postoperatively except in the general health domain. SF-36 role physical (RP) and bodily pain (BP) scores showed the most improvement (40.9 and 33.0 points in TKR and 36.9 and 31.4 points in UKA patients, respectively). The most substantial improvements between baseline and two years after surgery were in the physical domains of HRQoL (RP, BP, and physical functioning (PF)). In addition, in both groups, five domains of SF-36 (RP, BP, PF, social functioning, and role limitations due to emotional problems) reached the proposed minimal clinically important difference of ten points. TKR patients' SF-36 and OKS scores were not significantly different from those of UKA patients two year after surgery, except PF scores. Multiple regression analysis adjusting for sociodemographics showed that baseline scores were a significant predictor of the postoperative scores of OKS and all SF-36 subscales ($p < 0.01$), whereas the type of surgery was not associated with the postoperative scores. **CONCLUSIONS:** Both TKR and UKA patients experienced significant improvements in HRQoL, particularly in the RP and BP domains. After controlling for potential confounding variables, the type of surgery was not a significant predictor of patients' postoperative HRQoL scores.

PMS58

CLINICAL OUTCOMES AND CHANGES IN QUALITY OF LIFE IN WOMEN WITH OSTEOPOROSIS TREATED WITH TERIPARATIDE: 36 MONTH RESULTS OF THE FRENCH PATIENTS PARTICIPATING IN THE EUROPEAN FORSTEO OBSERVATIONAL STUDY (EFOS)

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OBJECTIVES: To describe back pain, and HRQoL in postmenopausal women with osteoporosis treated with teriparatide (Forsteo®) in France. **METHODS:** European, prospective, observational study of 36 months duration (18-month active treatment phase and 18-month post-treatment follow up) in postmenopausal women with osteoporosis who initiated teriparatide. HRQoL measured by EQ-5D and back pain measured by a Visual Analogue Scale (VAS) and a questionnaire were collected at each follow-up visit. **RESULTS:** Among 309 patients enrolled in France (18.8% of the total EFOS cohort), 290 (94.5%) had any follow-up data, and 201 (65.0%) completed the last post-treatment visit. At baseline, patients were 73.8 (7.4) years old (mean (SD)),

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 57.1% 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.

PMS59

THE EFFECT OF TNF THERAPY, SOCIODEMOGRAPHIC AND CLINICAL FACTORS ON SLEEP DISTURBANCES AND FATIGUE AMONG RHEUMATOID ARTHRITIS—RESULTS FROM THE NDB-PORTUGAL 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 (fatigue scale (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 0–3, 3 is worst), quality of life (VASQOL 0–1, 1 is better), 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 (–0.60 (–1.08, –0.11)) when compared to traditional DMARDs and although not statistically significant, decreased sleep disturbances (–0.46 (–1.04, 0.13)) and insomnia (–0.22 (–1.16, 0.73)). An increase in sleep disturbances was seen with worse HAQ (0.64 (0.25, 1.02)), lower VASQOL: (–1.46 (–2.63, –0.28)), more anxiety symptoms: (0.19 (0.09, 0.29)) and higher fatigue (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.

PMS60

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

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OBJECTIVES: Many studies have identified predictors of the health assement 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 646 RA patients from the ongoing biannual NDB-Portugal 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 a 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 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: 1.003 (95%CI: (1.000; 1.005))), age (OR: 1.02 (1.01; 1.02)) 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.

PMS61

RELATING OSTEOARTHRITIS 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) affectation, 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. Descriptives were used for 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 activities' (mean = 1.172; SD = 0.957) and 'reach' (mean = 1.127; SD = 0.912) were the HAQ-DI categories that showed higher disability. The SEM presented OA, disability and QoL as latent, related variables. 92% of QoL was accounted for disability (R-squared = 0.92). The global model that depicts OA as causing disability, and disability affecting QoL, has a marginal adjustment (CMIN/DF = 5.42; RMR = 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 fails to fully explain this link. As statistical techniques need good measurement models to correctly estimate relationships, standard clinical records seem insufficient for this purpose. Additional valid measurements of OA affectation would be needed, to give evidence of its direct effect on disability and QoL.

PMS62

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 III trial were randomised to CZP 400 mg administered 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 (BL). 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. FAST4WARD:NCT00548834; OLE:NCT00160693. **RESULTS:** Sixty-nine CZP completers entered the OLE. At BL: mean disease duration: 9.5 years; mean HAQ-DI: 1.42; mean DAS28-3(CRP): 5.76. Burden of RA on household productivity at BL was substantial: mean 10.1 household work days missed/month, mean 12.1 household work days with reduced productivity/month, mean 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 household, and 11.9, 57.7 and 107.2 days gained of 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.