

## PMS74

## INADEQUATE PAIN RELIEF AMONG PATIENTS WITH PRIMARY KNEE OSTEOARTHRITIS - ANALYSIS FROM THE PORTUGUESE SAMPLE OF THE SURVEY OF OSTEOARTHRITIS REAL WORLD THERAPIES (SORT)

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**OBJECTIVES:** Despite widespread treatments for Osteoarthritis (OA), data on treatment patterns, adequacy of pain relief, and quality of life are limited. The prospective multinational Survey of Osteoarthritis Real World Therapies (SORT) was designed to investigate these aspects. This analysis aims to describe the clinical characteristics and the patient reported outcomes of the Portuguese dataset of SORT baseline. **METHODS:** The statistical analysis included, from January to December of 2011, 192 participants  $\geq 50$  years or older with primary knee OA from 7 health care centers in Portugal who were receiving oral or topical analgesics. Inadequate Pain Relief (IPR) was defined as a score  $> 4/10$  in item 5 of the Brief Pain Inventory (BPI), indicating moderate to severe pain. **RESULTS:** Overall, the median age was  $67.0 \pm 8.7$  years and 77.6% were female. Mean duration of knee OA was  $6.3 \pm 6.3$  years. IPR was reported by 52.0% of the patients. The most prescribed analgesics were NSAIDs (88.1%), alternative therapies, including glucosamine, chondroitin and hyaluronate (44.3%) and paracetamol (28.6%). Patients with IPR scored higher than non-IPR patients in WOMAC – Stiffness (61.0 vs 39.7,  $p < 0.001$ ) and WOMAC – physical function (59.2 vs 39.4,  $p < 0.001$ ), meaning worse condition. Patients with IPR had worse quality of life related to knee osteoarthritis as measured by the SF-12 questionnaire (fair/poor: 86.9% vs 72.0%,  $p < 0.001$ ). 62.0% of patients with IPR were dissatisfied or very dissatisfied with the effects of analgesics versus 34.0% of patients with non-IPR ( $p < 0.05$ ). **CONCLUSIONS:** Despite the use of analgesics, over half of the Portuguese patients in SORT reported moderate to severe knee pain. Worse outcomes were also observed in this group regarding other symptoms of knee OA and general quality of life. These findings suggest that if an improvement of pain management in knee OA can be achieved, it may have high impact on patients' lives.

## PMS75

## QUALITATIVE EQUIVALENCE BETWEEN A PAPER AND ELECTRONIC TABLET VERSION OF THE WOMAC@NRS3.1 AND PATIENT GLOBAL ASSESSMENT

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**OBJECTIVES:** Prior equivalence work with the WOMAC@ scale was published for the VAS scale and older touchscreen computer technology. Additional equivalence evaluation of the WOMAC@NRS3.1 and the Patient Global Assessment (PGA) in a newer tablet with stylus was needed to document suitability of this mode of data collection for these instruments in upcoming clinical trials. **METHODS:** A cross-sectional qualitative study was conducted involving cognitive and usability interviews with patients diagnosed with osteoarthritis of the hip or knee who were taking pain medication for their condition. Interviews were conducted in two waves of 10 participants each, with revisions to the PGA made in between the rounds, which allowed for changes to the electronic version to be evaluated. **RESULTS:** Mean age of the sample (N=20) was 66 years, (range 43-78), 90% over 60 years old; 60% were female; 95% were white; 75% were retired; 70% had completed secondary school or some college, while 30% had completed college or a post-graduate degree. In wave 1, minor issues were found with completing the WOMAC@, mainly with using the stylus to select responses and glare on the screen. There were no issues identified in interpreting the response scale. For the PGA, 50% (5/10) used the wrong recall period (48 hours or longer). The PGA recall period was revised from "at this time" to "over the past 24 hours" and bolded for emphasis. In wave 2, similar issues with glare and stylus response were found, while 80% used the correct recall period on the PGA, with 20% using 48 hours. **CONCLUSIONS:** The study showed excellent qualitative equivalence between the paper and electronic WOMAC@ with only minor usability issues. The two wave study design provided the opportunity to detect and make changes to the PGA recall period and formatting that showed improvement in the second wave.

## PMS76

## LONG-TERM MAINTENANCE OF IMPROVEMENTS IN MULTIPLE FACETS OF PSORIATIC ARTHRITIS WITH CERTOLIZUMAB PEGOL: 96-WEEK PATIENT-REPORTED OUTCOME RESULTS OF THE RAPID-PSA STUDY

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**OBJECTIVES:** To report the effect of certolizumab pegol (CZP), a PEGylated Fc-free anti-TNF, on patient-reported outcomes (PROs) in psoriatic arthritis (PsA) over 96 weeks (wks) of the RAPID-PSa trial. **METHODS:** The RAPID-PSa trial (NCT01087788) is double-blind and placebo-controlled to Wk24, dose-blind to Wk48 and open-label to Wk216. Patients had active PsA and had failed  $\geq 1$  DMARD. Patients originally randomized to CZP (200mg Q2W or 400mg Q4W, following 400mg loading dose at Wk0, Wk2, Wk4) continued on their assigned dose in the dose-blind phase and OLE. Here we present PRO data for the CZP-treated randomized set, including mean change from baseline (CFB) and Minimal Clinically Important Differences (MCIDs). Data were also analysed for CZP-randomized patients with (19.8%) or without (80.2%) prior anti-TNF exposure. Missing data were imputed by LOCF. Correlations between clinical outcomes and PROs were also investigated. **RESULTS:** Of 273 patients

randomized to CZP at Wk0, 91% completed Wk24, 87% Wk48, and 80% Wk96. Rapid improvements observed to Wk24 were maintained to Wk96 for pain (Wk24 and Wk96; CFB: -28.5 and -31.3; MCID: 69.2% and 66.3%), fatigue (Wk24 and Wk96; CFB: -2.0 and -2.4; MCID: 64.1% and 60.4%), HAQ-DI (Wk24 and Wk96; CFB: -0.48 and -0.52; MCID: 48.7% and 48.0%), SF-36 PCS (Wk24 and Wk96; CFB: 8.01 and 9.01; MCID: 67.4% and 60.1%), SF-36 MCS (Wk24 and Wk96; CFB: 4.50 and 3.92; MCID: 50.9% and 43.6%), PsAQoL (Wk24 and Wk96; CFB: -3.87 and -4.50), and DLQI (Wk24 and Wk96; CFB: -5.8 and -6.0; MCID: 40.7% and 41.0%). Similar improvements were observed with both dosing regimens and in patients with or without prior anti-TNF exposure. Correlations were observed between improvements in PROs and DAS28 (data not shown). **CONCLUSIONS:** Improvements observed to Wk24 in generic and disease-specific PROs were sustained to Wk96 of the RAPID-PSa trial for both CZP dosing regimens.

## PMS77

## USABILITY TESTING OF A NOVEL PAIN MEDICATION DIARY ADMINISTERED ELECTRONICALLY

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**OBJECTIVES:** Pain medication diaries have traditionally been collected via paper due to challenges of patients entering unlimited medications, units, dosages, and administration schedules. This study developed an electronic diary that permits site staff to enter medications that patients are taking, enables the patient to update medication taken and to enter new medications within the reporting period, and reduces the possibility of cheating behaviors during the study. Usability of this electronic diary was evaluated to ensure that patients in a clinical trial setting could successfully update their diaries in real-time to accurately track pain medication intake. **METHODS:** A cross-sectional qualitative study was conducted involving usability interviews with patients diagnosed with osteoarthritis of the hip or knee who were taking pain medication. Interviews were conducted in two waves of 10 participants each, allowing for evaluation of findings and revisions to the eDiary between waves. **RESULTS:** Mean age of the sample (N=20) was 66 years (range 43-78), 90% over 60 years old; 60% were female; 95% were white; 70% completed secondary school or some college. In wave 1, issues were noted with training, selecting responses, exiting to send data, and some wording. For wave 2, the training module was revised to more closely match the diary, wording was revised, and a screen added to facilitate exiting the diary. No issues were noted with training, 4 had trouble selecting responses, and 3 suggested additional instructions on the new screen. No additional changes were made following wave 2. **CONCLUSIONS:** The study showed it is possible to develop an electronic pain medication diary that allows patients to update their medications during a study. Extensive training was critical to the usability of the electronic version. The two wave study design provided the opportunity to detect and make changes to the eDiary with marked improvement in wave 2.

## PMS78

## QUALITY OF LIFE IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS IN CLINICAL PRACTICE IN SWEDEN: BASELINE RESULTS FROM A LONGITUDINAL STUDY

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**OBJECTIVES:** Spondyloarthritis (SpA) is a group of diseases that share common clinical, radiographic and genetic features. Axial SpA is one major subgroup including patients with radiographic (rad-axSpA) and non-radiographic axSpA (nr-axSpA). There has been limited research on axSpA patients in clinical practice and the impact of the disease on patient's health-related quality of life (HrQoL). The aim of this study was to characterize patients with axSpA in clinical practice and to investigate similarities/differences between rad-axSpA and nr-axSpA with respect to their HrQoL. **METHODS:** This is a longitudinal, multi-center cohort study where patients were consecutively recruited from Swedish clinical practice and followed for 3 months. At baseline, the rheumatologists registered information on disease history, extra articular manifestations and treatments. The patients answered online questionnaires capturing patient demographics, disease activity, function and HrQoL. HrQoL was measured using the EQ-5D and the Ankylosing Spondylitis Quality of Life Questionnaire (ASQoL). While higher scores in the EQ-5D indicate better HrQoL, the opposite is true for the ASQoL. **RESULTS:** 251 patients were included of whom 197 (78%) were classified as axial SpA. Of those, 125 (63%) were classified as rad-axSpA and 72 (37%) as nr-axSpA according to the ASAS axSpA criteria. There were more women in the nr-axSpA group (50%) compared with the rad-axSpA group (38%). The nr-axSpA patients had a shorter time between symptom onset and diagnosis than the rad-axSpA patients (6.7 vs. 9.0 years) and a significantly higher disease activity (BASDAI=4.1 vs 2.7,  $p < 0.001$ ). Mean EQ-5D score at baseline was 0.66 for rad-axSpA and 0.61 for nr-axSpA, lower than the Swedish general population (0.84). ASQoL scores was significantly higher in the nr-axSpA group (8.8 vs 6.4,  $p = 0.016$ ). **CONCLUSIONS:** HrQoL is poorer in axial SpA patients compared to the general population and patients with nr-axSpA reported a higher impact on HrQoL than patients with rad-axSpA.

## PMS79

## FUNCTIONAL STATUS, QUALITY OF LIFE AND WORK DISABILITY FOR PATIENTS WITH RHEUMATIC DISEASES IN GREECE

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**OBJECTIVES:** Rheumatic diseases (RD) have been associated with functional and work-related disability due to the deliberating and progressive nature of these diseases and have many deleterious consequences on patients' life. The aim of the