MUSCULAR-SKELETAL DISORDERS – Patient-Reported Outcomes & Patient Preference Studies

PMS64
EQ-5D STUDIES IN RHEUMATOLOGY IN EIGHT CENTRAL AND EASTERN EUROPEAN COUNTRIES

Péntek M[1], Rencz F[1], Golicki D[2], Prevolnik Rupel V[3], Simon J[4], Brodszky V[1], Baji P[1], Závada J[5], Zrubka Z[1], Petrova G[6], Rotar A[7], Gulácsi L[1]
[1]*Corvinus University of Budapest, Budapest, Hungary,* [2]*Department of Experimental & Clinical Pharmacology, Medical University of Warsaw, Warsaw, Poland,* [3]*Institute for Economic Research, Ljubljana, Slovenia,* [4]*Medical University of Vienna, Vienna, Austria,* [5]*Institute of Rheumatology, Prague, Czech Republic,* [6]*Medical University Sofia, Faculty of Pharmacy, and President, ISPOR Bulgaria Chapter, Sofia, Bulgaria,* [7]*University of Amsterdam, Amsterdam, The Netherlands*

OBJECTIVES: Cost-utility analyses using local data are required in several Central and Eastern European (CEE) countries for reimbursement decisions. The aim of this research was to analyse the available studies in rheumatic diseases in the CEE region using the EQ-5D, a preferred instrument to calculate quality-adjusted life years (QALY). **METHODS:** A systematic search was performed to identify EQ-5D studies using PubMed, EMBASE, Web of Science, CINAHL, PsycINFO, The Cochrane Library and the EuroQol Group database up to July 1, 2015. Also, authors handsearched local journals. Full-text articles reporting original research with EQ-5D instruments from Austria, Bulgaria, Czech Republic, Hungary, Poland, Romania, Slovakia or Slovenia were included. Studies on diseases of the musculoskeletal system and connective tissue were selected. **RESULTS:** From the 143 papers 23 dealt with rheumatic conditions, of which 15 (65%) were in English. The first study was launched in 2002. Most studies were from Hungary (65%) and none from Bulgaria or Romania. A total of 5434 patients were involved (n=patients/studies: osteoporosis 2685/4; rheumatoid arthritis-RA 1666/6; hip replacement 274/2; low back pain 268/4; psoriatic arthritis 240/2; osteoarthritis 175/3; systemic sclerosis 80/1; chronic shoulder pain 46/1). There were 11 cohorts (1 registry), 7 cross-sectional studies and 5 randomized controlled trials. No studies with the EQ-5D-5L were found. EQ-5D utility scores were reported in 19 (83%) papers but in 10 of them the applied tariff was not specified. The average utility scores of biological drug-naive RA samples were comparable (0.36-0.48) across studies. **CONCLUSIONS:** An increasing but heterogeneous EQ-5D research activity can be observed in rheumatology in the CEE region. Paediatric studies and data from clinical areas with costly treatments such as ankylosing spondylitis and systemic lupus are lacking. Inter-country collaborations and joint research planning are encouraged to efficiently expand the availability of utility data for cost-effectiveness studies in the region.

PMS65
PATIENT FOCUSED TECHNOLOGY ENABLED PROGRAMS IMPROVE OUTCOMES IN PRIMARY TOTAL HIP (THA) & TOTAL KNEE ARTHROPLASTY (TKA) PATIENTS

Jayakumar P[1], Di J[2], Fu J[2], Craig J[3], Joughin V[4], Babaei-Mahani A[5], Nadarajah V[6], Cope J[6], Bankes M[6], Earnshaw P[6], Shah Z[6]
[1]*University of Oxford / Johnson & Johnson Medical Devices. UK, High Wycombe, UK,* [2]*Janssen Healthcare Innovation. Division of Janssen Cilag Ltd., High Wycombe, UK,* [3]*York Health Economics Consortium, York, UK,* [4]*Johnson and Johnson Medical Devices, Leeds, UK,* [5]*Johnson and Johnson Innovations, London, UK,* [6]*Guys and St Thomas Hospital NHS Trust, London, UK*

OBJECTIVES: A program integrating technological enhancement of patient engagement and pathway management, with enhanced recovery (ER) in primary THA and TKA surgery was assessed. Primary objectives assessed impact on length of stay (LoS) and readmission rates. Secondary objectives assessed impact on clinical and patient-focused outcomes. **METHODS:** 2126 consecutive THA (n=1063) and TKA (n=1063) patients were divided into pre-solution (n=1036) and post-solution groups (n=1090). Post-solution patients were subdivided by criterion-based eligibility for outreach support (OS). All patients underwent service and clinical outcomes assessment whilst a smaller cohort (n=229) completed PROMs and satisfaction ratings. **RESULTS:** Medical complexity was high (ASA grade 3+, 25.5% THA, 32% TKA; 16% UK average, 2014; Charlson co-morbidity index, mean 3.2 +/- 2.27 (sd) THA; mean 4.1 +/- 1.96 (sd) in TKA). Mean LoS significantly reduced post-program (4.8d to 3.4d THA; 5.6d to 4.0d TKA) ($p<0.001$) with no negative trends in 30d readmissions. Clinical outcomes (complication, reoperation and re-attendance) were numerically improved but not statistically significant. OHS improved in THA (OS) patients (health gain 24.231 vs. 21.294, UK average, 2014) ($p<0.001$) and OKS improved in TKA (NOS) patients (16.713 vs. 16.241, UK national average, 2014) ($p<0.002$). General health numerical rating was higher in all groups (health gain 1.7 – 2.3 THA; 1.2 – 2 TKA) ($p<0.002$) as was patient experience in all domains at up to 6 months follow-up ($p<0.001$ to $p=0.003$). Cost evaluation demonstrated total potential savings of £250,331 per annum (£401.64 per THA; £76.67 per TKA patient), deducting program costs with savings following LoS reductions. **CONCLUSIONS:** Currently, few programs integrate patient engagement & pathway management features with ER practices and technology. Programs of this nature can drive clinical effective delivery of care reducing LoS without negatively impacting clinical outcomes. Patient-reported outcomes & experience can be improved and even the more medically complex patients with greater needs may benefit.

PMS66
A DISCUSSION ON COPING: TRANSLATION OF THE EULAR PSORIATIC ARTHRITIS IMPACT OF DISEASE: PSAID-9 FOR CLINICAL TRIALS IN 19 LANGUAGES FOR 18 COUNTRIES

Brandt B[1], McKown S[1], Gawlicki M[1], Angün Ç[1], Yohe Moore E[2]
[1]*Corporate Translations Inc, East Hartford, CT, USA,* [2]*Corporate Translations Inc, Chicago, IL, USA*

OBJECTIVES: To evaluate variation in translation of the terms coping and cope in the EULAR Psoriatic Arthritis Impact of Disease: PsAID-9, and to provide recommendations for measuring this domain moving forward. The PsAID-9 is a self-administered questionnaire developed to assess the impact of psoriatic arthritis (PsA) on patients (Gossec et al., 2014). The PsAID-9 measures 9 domains: pain, fatigue, skin problems, work and/or leisure activities, functional capacity, discomfort, sleep disturbance, coping, anxiety, fear and uncertainty. Coping is defined as "the specific efforts, both behavioral and psychological, that people employ to master, tolerate, reduce, or minimize stressful events" (Taylor, 1998). **METHODS:** Corporate Translations, Inc., translated and back-translated the PsAID9 into 19 languages for 18 countries. The English back-translations were then reviewed by a project manager and survey research analyst; revisions to translations were made as needed to improve clarity and conceptual equivalence with the source. Back-translations of the terms coping and copewere compared across languages and any variations were noted. **RESULTS:** Comparison of the back-translations of the PsAID9 revealed variation in the interpretation of coping. Coping encompasses elements of emotional, physical, and logistical adaptation, resulting in the diversity of translations shown in this sample. Interpretations of coping as adaptation to the emotional demands of PsA were translated as getting used to, resigned to, or living with. Interpretations of coping as adaptation to the physical limitations of PsA were translated as adapted to or adjusted to, and interpretations as practical adaptation to the logistical demands of the PsA were translated as manage, handle, or deal with. **CONCLUSIONS:** The terms coping and copehave multiple interpretations due to their many facets of meaning. Investigators and COA developers should bear this in mind, and consider including items measuring the specific coping modes of interest, to avoid potential issues with pooling data across languages.

PMS67
WORK PRODUCTIVITY/INTERFERENCE AND GENERAL HEALTH STATUS IMPROVEMENTS WITH SIRUKUMAB, AN ANTI-IL-6 CYTOKINE MONOCLONAL ANTIBODY, IN PATIENTS WITH ACTIVE RHEUMATOID ARTHRITIS DESPITE TREATMENT WITH DISEASE-MODIFYING ANTI-RHEUMATIC DRUGS: RESULTS FROM THE PHASE 3 SIRROUND-D STUDY

Takeuchi T[1], Karpouzas G[2], Thorne C[3], McQuarrie K[4], Sheng S[4], Xu W[4], Peterson S[4], Ganguly R[5], Han C[4], Fei K[4], Hsu B[4]
[1]*Division of Rheumatology, Keio University School of Medicine, Tokyo, Japan,* [2]*Division of Rheumatology, Harbor-UCLA Medical Center, Torrance, CA, USA,* [3]*University of Toronto and Southlake Regional Health Centre, Newmarket, ON, Canada,* [4]*Janssen Research & Development, LLC, Spring House, PA, USA,* [5]*GlaxoSmithKline, Collegeville, PA, USA*

OBJECTIVES: This study evaluated effects of sirukumab, a selective, high-affinity anti-IL-6 cytokine monoclonal antibody, on the key treatment-related outcomes of work productivity/interference and general health status in patients with active rheumatoid arthritis (RA) despite treatment with disease-modifying antirheumatic drugs (DMARDs). **METHODS:** Eligible patients were randomized 1:1:1 to sirukumab subcutaneous (SC) 50mg q4w, sirukumab SC 100mg q2w, or placebo SC q2w. Patients receiving placebo with <20% improvement at Weeks 18 or 40 or still on placebo at Week 52 were re-randomized to 1 of the 2 sirukumab dosages. The Work Limitations Questionnaire (WLQ) evaluated health-related job limitations and productivity loss; the 3-level EuroQol-5 Dimension (EQ-5D) questionnaire measured 5 dimensions of health status (mobility, self-care, usual activities, pain/discomfort, anxiety/depression). Additional endpoints included changes from baseline in WLQ scores, EQ-5D index scores, and EQ-5D health state visual analog scale (VAS) scores at Weeks 24 and 52. **RESULTS:** There were significant improvements in mean WLQ production loss scores from baseline for sirukumab 50mg q4w and 100mg q2w compared with placebo at Weeks 24 and 52 (both $P<0.001$; mean Week 52 change, -3.06 and -2.94 vs -0.73, respectively). Both doses of sirukumab led to significantly greater improvements from baseline in all 4 mean WLQ domain scores (mental-interpersonal, output, physical demands, time management) compared with placebo at Weeks 24 and 52 (all $P<0.05$). The mean EQ-5D index and health state VAS scores improved significantly from baseline at Weeks 24 and 52 with both doses of sirukumab compared with placebo (all $P\leq0.002$; mean Week 52 index change, 0.20 and 0.20 vs 0.13, respectively; mean Week 52 VAS change, 16.80 and 17.14 vs 8.30, respectively). **CONCLUSIONS:** Sirukumab treatment led to significant improvements in work-related productivity and general health status in patients with active RA refractory to DMARDs, consistent with the demonstrated effects of sirukumab on RA disease improvement.

PMS68
PATIENTS' PREFERENCES TOWARD CHARACTERISTICS OF TREATMENT WITH BIOLOGICAL AGENTS DIFFER ACCORDING TO EXPERIENCE WITH THEIR RHEUMATIC DISEASE AND TREATMENT RECEIVED OR PRESCRIBED: RESULTS FROM THE CARA STUDY

Cortesi PA[1], Scalone L[1], Sinigaglia L[2], Sarzi-Puttini P[3], Montecucco C[4], Giacomelli R[5], Lapadula G[6], Olivieri I[7], Giardino AM[8], Mecchia M[8], Mantovani LG[1]
[1]*University of Milano-Bicocca, Monza, Italy,* [2]*G. Pini Hospital, Milan, Italy,* [3]*L. Sacco University Hospital, Milan, Italy,* [4]*University of Pavia, Pavia, Italy,* [5]*University of L'Aquila, L'Aquila, Italy,* [6]*University of Bari, Bari, Italy,* [7]*Rheumatology Department of Lucania, San Carlo Hospital of Potenza and Madonna delle Grazie Hospital of Matera, Matera, Italy,* [8]*MSD Italy, Rome, Italy*

OBJECTIVES: to estimate preferences of relevant treatment characteristics valued by the different subjects involved in the management of patients with rheumatic diseases. This abstract focuses on patients' preferences. **METHODS:** We involved patients with rheumatoid arthritis (RA), ankylosing spondylitis (AS) or psoriatic arthritis (PA), who according to clinical practice, at the time of data collection had a new prescription of (naïve), or received treatment with (experienced) biological drugs for at least 3 months in the last 12 months. Through a Discrete-Choice-Experiment, the participants valued 16 possible scenarios in which pairs of similarly effective treatments were described with 6 characteristics including 2-4 possible levels each: (1) frequency of administration; (2) mode and place of administration; (3) hospitality, service, efficiency and courtesy of health personnel; (4) frequency of reactions at the site of drug administration; (5) generalized undesired reactions or allergic reactions involving the whole body; (6) additional contribution added as healthcare taxes to be paid by all the citizens to make available the treatment to target patients. **RESULTS:** 513 patients from 30 centres through Italy participated, balanced for diagnosis and treatment experience (around 20% of each subgroup).