PM107

PATIENT-REPORTED OUTCOMES IN STUDIES PUBLISHED IN 2014: WHICH TOOLS HAVE BEEN MOST COMMONLY USED IN STUDIES OF MUSCULOSKELETAL DISEASES?

Martin A
Crysarix Ltd., London, UK

OBJECTIVES: To determine which patient-reported outcome (PRO) tools were used in studies on musculoskeletal diseases published in 2014. METHODS: An evidence surveillance process was established based on a systematic search of PubMed, incorporating all studies published from 2010 and updated weekly, with a final search on 18 May 2015. Abstracts identified by the search that reported quality of life outcomes in musculoskeletal disorders were identified. Articles were included if they reported results or a study protocol results of a primary research study or were a systematic review. PRO tools were identified from the abstract alone, where possible. RESULTS: The search identified 1,980 articles published in 2014. Of these, 597 (30%) were in musculoskeletal disorders. The most commonly researched diseases were osteoarthritis (19 articles), rheumatoid arthritis and back pain (14 each), fibromyalgia and fractures (10 each), and ankylosing spondylitis (9). Overall, 160 different PRO or clinician-reported instruments were cited in the 197 abstracts, with 93 articles citing more than one tool. Pain instruments were most commonly used (82 articles included either VAS or unspecified pain measurement). Utility measurement was made in 36 studies, with SF-36 used twice as often as either SF-12 or EQ-5D. PROs most commonly cited included WOMAC (13 articles), DASH (9), KOOS (9), HAQ (8), WHQOL-BREF (6), FIQ and WOSI (5 each). The PRO tool was not used in specific 52 article abstracts. 22 of the 143 primary research articles, 7 of 18 study protocols and 3 of 34 systematic reviews. CONCLUSIONS: A wide range of musculoskeletal disorders were researched in 2014, with little overlap in PRO tools used even within diseases. Standardisation of tool use would aid comparison of outcomes across studies. Evidence surveillance including study protocols, results and systematic reviews may help identify trends in PRO use within specific diseases.

PM108

PRO CLAIMS IN FIBROMYALGIA: A REVIEW OF THE LABELS OF PRODUCTS APPROVED BY THE FDA AND THE EMA

Acquaviva C1, Ferretti C, Begnaoui A2
1Magi Research Trust, Lyon, France, 2Magi, Lyon, France

OBJECTIVES: Fibromyalgia is a chronic pain syndrome characterized by increased sensitivity to pain, fatigue, muscle stiffness, difficulty sleeping, problems with mental processes (known as "fibro-fog"), such as problems with memory and concentration, headaches, and irritable bowel syndrome. The objectives of this study were to: 1) identify patient-reported outcome (PRO) claims in products specifically approved for fibromyalgia in the USA and European Union from the FDA and the European Medicines Agency (EMA) since 1995, and 2) to identify the endpoint positioning of the PROs when measured. METHODS: The websites of the FDA and the EMA were explored to identify all products approved specifically for fibromyalgia. PRO labels were used to identify products with a PRO claim in label. All corresponding clinical reviews (FDA), and assessments reports (EMA) were reviewed to check for endpoint positioning. RESULTS: Since 1995, only three products have been approved with the specific fibromyalgia label (three by the FDA, i.e., duloxetine, milnacipran and pregabalin). None have been approved by the EMA. All of the products approved by the FDA include PRO claims in their labels: reduction in pain, improvement in patient global impression of change (PGIC) when the medical review was available (duloxetine, milnacipran), and improvement in disability (HAQ-DI) when the medical review was not available (pregabalin). The PRO was considered as a primary endpoint. Function was a secondary endpoint measured either by the Fibromyalgia Impact Questionnaire (duloxetine, pregabalin) or the SF-36 Physical Component Summary (milnacipran). CONCLUSIONS: PROs are essential to the evaluation of fibromyalgia products and are included in the labels of all products approved by the FDA. Reduction in pain is the key primary endpoint.

PM109

UNDERSTANDING THE RELATIONSHIP BETWEEN HEALTH ASSESSMENT QUESTIONNAIRE (HAQ-DI), FIBROMYALGIA SEVERITY INDEX (FMSI), AND QUALITY OF LIFE (QOL) AND ITS INFLUENCE ON COST-EFFECTIVENESS IN PSORIATIC ARTHRITIS (PSA)

Gundu P, Syeda S3, Jugi Shrestha4, A653
1Novartis Healthcare Pvt. Ltd., Hyderabad, India, 2Novartis Pharma AG, Basel, Switzerland

OBJECTIVES: To evaluate the relationship between the disease activity measures (HAQ-DI, PASI) and patient’s QoL based on different utility mappings and its influence on cost-effectiveness (CE) METHODS: The identified algorithms of a literature research project that includes database screening of publications in English language, have been extracted and the different tools used in 6 months. Outcomes included: EuroQol-5D (EQ-5D) (Harrigan et al. 2007) and the different algorithms used to derive utility. University of Alabama (n=245) PSa patients based on clinical study data. In these studies, utilities were measured either with the SF-36 (n=5) or the EQ-5D (n=9) instruments. Different algorithms used different independent variables such as HAQ-DI, PASI or Disease Activity Score 28 (DAS28). The SF-36 was the reference standard in the first 12 weeks and Markov structure for rest of the time horizon with three month cycle lengths. All three tools research retrieved 11 different algorithms to derive utility for each patient. RESULTS: The utility was measured either through HAQ-DI (n=11) or DAS28 (n=2), whereas PASI was used for the skin component (n=4). Most of the algorithms were using a linear approach (n=11). Among these linear algorithms a unit decrease of HAQ-DI improves patient’s utility by 0.1 to 0.3 units. Effect of PASI on utility was much smaller as compared to HAQ-DI (0.004 improvement in utility per unit decrease in PASI). Using these algorithms, the incremental cost-effectiveness ratios (ICER) were calculated for each biologic versus standard of care. For each biologic ICERs coefficient of variation (standard deviation/mean) was approx. 17%.

PM110

THE ASSOCIATION BETWEEN DISEASE ACTIVITY AND QUALITY OF LIFE AMONG PATIENTS WITH ANKYLOSING SPONDYLITIS IN POLISH POPULATION

Malinowski K, Kwalew P
Jagiellonian University Medical College Institute of Public Health, Krakow, Poland

OBJECTIVES: The aim of this study was to assess the association between the disease activity and quality of life of patients with ankylosing spondylitis (AS) in Polish population. METHODS: On-line questionnaire survey was performed to obtain data on disease activity and the quality of life. We used Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) to assess the disease activity and Short Form-36 (SF-36) to assess the quality of life of patients with ankylosing spondylitis (AS) in Polish population. RESULTS: A total number of 66 questionnaires was obtained. Patients reported mostly the problems with general discomfort and morning stiffness represented by 8 points on BASDAI scale, followed by tiredness and neck pain represented by 7 points and other pain represented by 5 points. There were no observed that morning stiffness lasts longer than two hours. The mean BASDAI score was 5.87 (SD: 1.81). All of patients, 68% reported some (highest reported state) problems with mobility, 47% with looking after himself. A lot (highest reported state) of problems with usual activities reported 4% of patients, a lot of pain and discomfort was reported by 13% of patients and with feeling worried by 6%. In all domains “some problems” was the most frequent answer resulting that the BASDAI EQ-5D standard was 0.803. The PRO used was not specified in 52 abstract alone, where possible.

PM111

AVOIDABLE BURDEN AND UNMET NEED ASSOCIATED WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS TREATMENT: A CROSS-SECTIONAL EUROPEAN STUDY IN THE REAL WORLD SETTING

Holbrook Y1, Wood R1, Mutebi A2, Sawant RV3, Piercy J4, Harrison DJ5
1Kings College Hospital, London, UK, 2Adelphi Real World, Bollington, UK, 3Amgen Inc., Thousand Oaks, CA, USA

ABSTRACT: A653

OBJECTIVES: Non-radiographic axial spondyloarthritis (nr-axSpA) is an inflammatory condition primarily affecting the axial skeleton and is characterized by chronic back pain affecting more than 1.6% of the European population. The aim of this study was to conduct a cross-sectional investigation of nr-axSpA patients, to assess their burden of disease, and to identify areas of unmet need. METHODS: Patients were recruited from rheumatologist and inflammatory back pain (69.5% vs. 38.5%) (all p < 0.05). Patients received both biologic and non-biologic therapies. By the physician were compared to patients receiving biologics for nr-axSpA. There were no observed differences between cohorts regarding mean EQ-5D utility score (0.81 v. 0.82) or EQ-VAS (65.5 v. 64.8). CONCLUSIONS: A potential unmet has been highlighted in nr-axSpA patient management, which could be due to restrictions upon physicians prescribing choices. Reducing the duration between diagnosis and biologic treatment prescription could potentially lessen the societal and clinical burden of nr-axSpA.

PM112

BURDEN OF RESIDUAL SKIN AND JOINT DISEASE IN PATIENTS WITH PSORIATIC ARTHRITIS TREATED WITH BIOLOGICS

Woodcock V1, Watson A, Browne J2, Sawant RV3, Harrigan D4
1Adelphi Real World, Macclesfield, UK, 2A653, Thousand Oaks, CA, CA, USA, 3Kings College Hospital, London, UK, 4Adelphi Real World.

ABSTRACT: A653

OBJECTIVES: To describe residual skin and joint disease and health-related quality of life (HRQoL) in psoriatic arthritis (PsA) patients treated with biologics, and to explore the impact of residual disease on HRQoL, work productivity, and switching therapies. METHODS: This was a retrospective analysis of 2013-14 EU-ES Adelphi Real World cross-sectional survey data from dermatologists, rheumatologists, and PsA patients receiving biologics for ≥6 months. Outcomes included: EuroQol-5 Dimension (EQ-5D), Health Assessment Questionnaire Disability Index (HAQ-DI), PROMIS-HAQ (dermatologists), Dermatology Life Quality index
PMS113
ESTIMATING THE MONETARY VALUE OF RELIEF OF TENNIS ELBOW: A CONTINGENT VALUATION STUDY OF WILLINGNESS-TO-PAY
Peirena MJ1, Gombos BKC, Bisset LM1, Vicenzino B2, Connelly L1
1University of Queensland, Brisbane, Australia, 2Griffith University, Gold Coast, Australia
OBJECTIVES: To estimate the willingness-to-pay (WTP) for symptom relief of tennis elbow. The examination of how much WTP is related to outcomes, or other socio-demographic factors. METHODS: This cross-sectional WTP contingent valuation study was performed alongside a randomised controlled trial comparing the efficacy and safety of physical therapy vs. corticosteroid injections in participants with tennis elbow. The contingent value scenario constructed required participants to decide the monetary value (AUD) they would pay for a quick and non-invasive treatment for relief of pain and loss of function in the arm for 1 month (condition). We also told to consider that their symptoms would persist for the next 12 months if left untreated. The efficacy of this new treatment was defined as complete recovery in 50% of patients. WTP of 2 patient groups. The bidding game approach was performed in 87 participants. The binary response approach was performed in 87 participants. All participants accepted a $50 bid, while more than half accepted $650 and $1250. Participants were more likely to accept bids that were more related to their values if they had experienced greater pain and disability, a worsening condition and reduced pain-free grip of their affected arm. CONCLUSIONS: This study examined the economic value that patients with tennis elbow ascribe to relief of their condition. The relationship between this monetary value and an individual’s injury characteristics and income was also demonstrated. In future work, we propose to compare these WTP estimates with indicators of health-related quality-of-life, which were also collected during this study.

PMS114
CLINICAL RESPONSES IN JOINT AND SKIN OUTCOMES AND PATIENT-REPORTED OUTCOMES ARE ASSOCIATED WITH INCREASED PRODUCTIVITY IN THE WORKPLACE AND AT HOME IN PSORIATIC ARTHRITIS PATIENTS TREATED WITH CERTOLIZUMAB PEGOL
van der Heijde D1, Braun P, Rudwaleit M1, Furck C1, Ovaa C1
1Leiden University Medical Center, Leiden, The Netherlands, 2Rheumazentrum Rhein-Neckar, Heidelberg, Germany, 3Klinikum Bielefeld Rosenhöhe, Bielefeld, Germany, 4UCB Pharma, Brussels, Belgium, 5University of California, San Diego School of Medicine, La Jolla, CA, USA
OBJECTIVES: To evaluate the association between improvements in clinical and patient-reported outcomes (PROs) and improvements in workplace and household productivity in axSpA patients treated with certolizumab pegol, including ankylosing spondylitis (AS) and non-radio-graphic axSpA (nr-axSpA). METHODS: Analyses used Week (Wk) 24 data from the double-blind, placebo-controlled period of RAPID-axSpA (NCT01087762), for patients treated with certolizumab pegol. Cases of clinical and PRO outcomes and PROs were compared in terms of change from baseline (CBF) in workplace and household productivity, assessed with the arthritis-specific Work Productivity Survey (WPS). Groups were compared using a non-parametric biomarker analysis for ASDAS and WPS outcomes. NRI for ASAS40 and ASAS50. RESULTS: 218 CZP patients entering RAPID-axSpA were analysed at Wk24 (121 AS, 97 nr-axSpA). Patients employed at Wk24: 73.6% axSpA, 73.6% AS, 74.2% nr-axSpA. Greater improvements in workplace productivity were reported by CZP-treated axSpA patients who achieved a clinical response (pres-enteeism CBF [responders/non-responders]: -3.9/-1.0 for ASAS40; -4.3/0.7 for ASDAS-MI) and reported improved functional physical and less back pain (pres-enteeism CBF: -3.9/0.7 for BASMI; -3.7/4.5 for total back pain MCID)). Clinical responses and symptom relief were also associated with improved household productivity (CBF in days with productivity reduced by ≤1 h in responders/non-responders: -3.1/-1.8 for ASAS40; -5.1/-2.2 for ASAS-MI; -5.6/-0.6 for ASAS-MI; -5.2/-0.6 for ASAS-MI) and greater social participation (CBF in family/social/leisure days missed [responders/non-responders]: -3.3/1.8 for ASAS-MI, -4.3/1.9 for ASAS-MI, -5.0/-0.5 in nr-axSpA; -3.4/-0.9 in AS). Results should be interpreted with caution, given differences in patient number between groups. NRI for CBF were undetermined for baseline productivity differences. CONCLUSIONS: Achievement of clinical responses and symptom relief were associated with increased workplace and household productivity in CZP-treated axSpA patients, including AS and nr-axSpA. MUSCULAR-SKELETAL DISORDERS - Health Care Use & Policy Studies

PMS116
ELDERLY OSTEOPOROSIS SUSPECTS WITHOUT DIAGNOSIS – INTERIM DATA FROM A GERMAN GERIATRIC PRACTICE
Schmid T1, Brunme UM2, Kemere S3, Zimmer K2
1Amgen GmbH, Munich, Germany, 2Lenzigers Gesundheitsnetz e.V., Leizpig, Germany
OBJECTIVES: Elderly patients are at higher risk for osteoporotic (OP) fractures compared with the general population[1], with low-trauma fractures in elderly patients associated with increased mortality risk[2]. In a high proportion of patients with an OP fracture, OP is previously undiagnosed and no OP-medication initiated[3]. This study aims to research the risk in OP-fracture suspects without OP-diagnosis. [1] Cooper C et al. (1992): Hip fractures in the elderly: a world-wide pro-
al examination. [2] Blüeic et al.: Mortality risk associ-
METHODOLOGY: Our data suggest proactive evaluation of patients with osteoporotic risk factors was inadequate in elderly patients aged ≥ 70 years. A prospective, observational, case-control study of OP-fracture suspects was performed. Elderly patients were at higher risk for osteoporotic (OP) fractures compared with the general population[1], with low-trauma fractures in elderly patients associated with increased mortality risk[2]. In a high proportion of patients with an OP fracture, OP is previously undiagnosed and no OP-medication initiated[3]. This study aims to research the risk in OP-fracture suspects without OP-diagnosis. [1] Cooper C et al. (1992): Hip fractures in the elderly: a world-wide pro-
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